US007100617B1

(12) **United States Patent**
Maginot

(10) **Patent No.: US 7,100,617 B1**
(45) **Date of Patent: *Sep. 5, 2006**

(54) **BYPASS GRAFTING METHOD**

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(73) Assignee: **CardioThoracic Systems, Inc.**, Santa Clara, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/726,803**

(22) Filed: **Dec. 2, 2003**

Related U.S. Application Data

(60) Continuation of application No. 09/903,831, filed on Jul. 11, 2001, which is a continuation of application No. 09/475,789, filed on Dec. 30, 1999, now Pat. No. 6,599,313, which is a continuation of application No. 09/111,062, filed on Jul. 7, 1998, now abandoned, which is a continuation of application No. 09/090,598, filed on Jun. 4, 1998, now Pat. No. 5,934,286, which is a continuation of application No. 09/073,336, filed on May 5, 1998, now Pat. No. 5,979,455, which is a continuation of application No. 08/702,742, filed on Aug. 23, 1996, now Pat. No. 5,749,375, which is a continuation of application No. 08/391,960, filed on Feb. 21, 1995, now Pat. No. 5,571,167, which is a continuation of application No. 08/138,912, filed on Oct. 18, 1993, now Pat. No. 5,456,712, which is a division of application No. 08/056,371, filed on May 3, 1993, now Pat. No. 5,304,220, which is a continuation-in-part of application No. 07/725,597, filed on Jul. 3, 1991, now Pat. No. 5,211,683.

(51) **Int. Cl.**
A61F 2/06 (2006.01)
A61B 17/08 (2006.01)

(52) **U.S. Cl.** **128/898**; 623/1.11; 623/902; 606/154; 604/8

(58) **Field of Classification Search** 604/8; 606/153, 154, 155, 108; 623/1.11, 902, 903; 128/898

See application file for complete search history.

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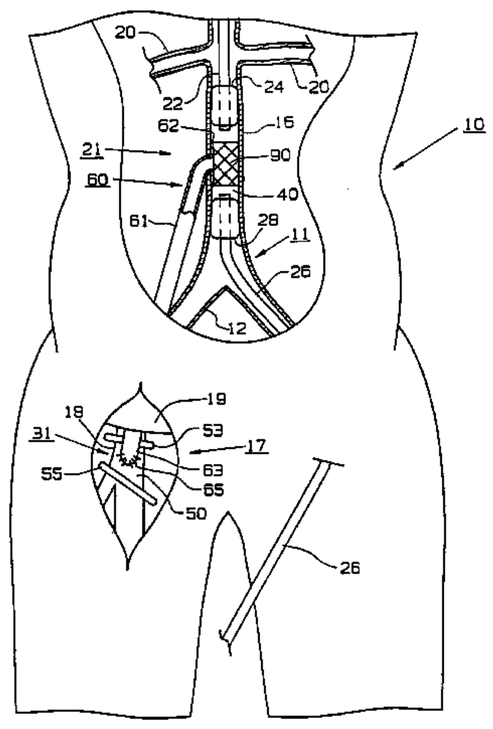
(57) **ABSTRACT**

Minimally invasive techniques utilized in bypass grafting are disclosed. For instance, a method of implanting an end portion of a graft in the body of a patient during a bypass grafting procedure includes the steps of (i) advancing a medical instrument within a circulatory system of said body, (ii) guiding a distal end of said medical instrument out of said circulatory system through an opening defined in said circulatory system after said medical instrument advancing step, (iii) advancing said end portion of said graft within said medical instrument after said guiding step, and (iv) securing said end portion of said graft to a blood vessel of said circulatory system after said end portion advancing step.

4 Claims, 36 Drawing Sheets



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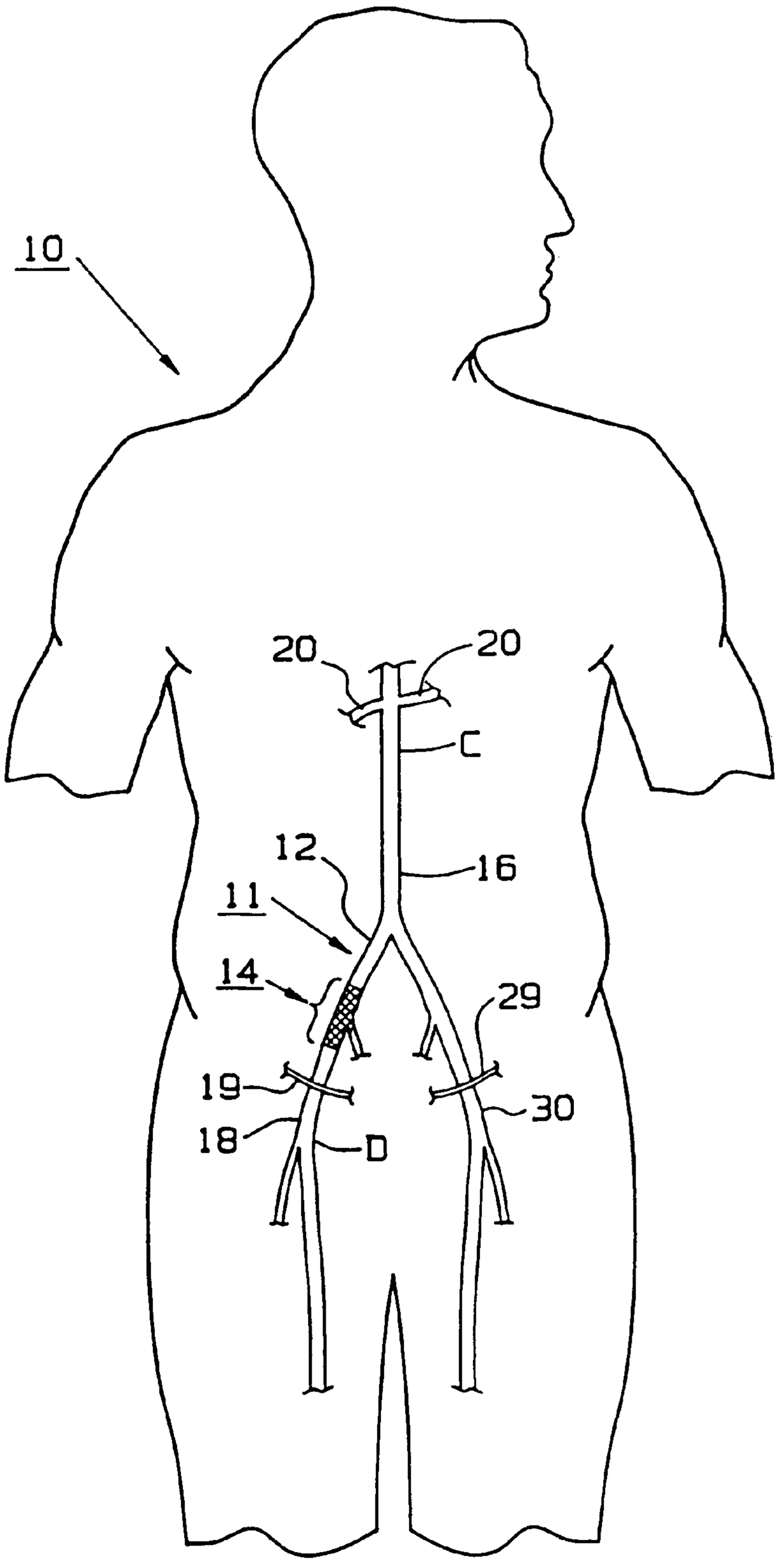


Fig. 1

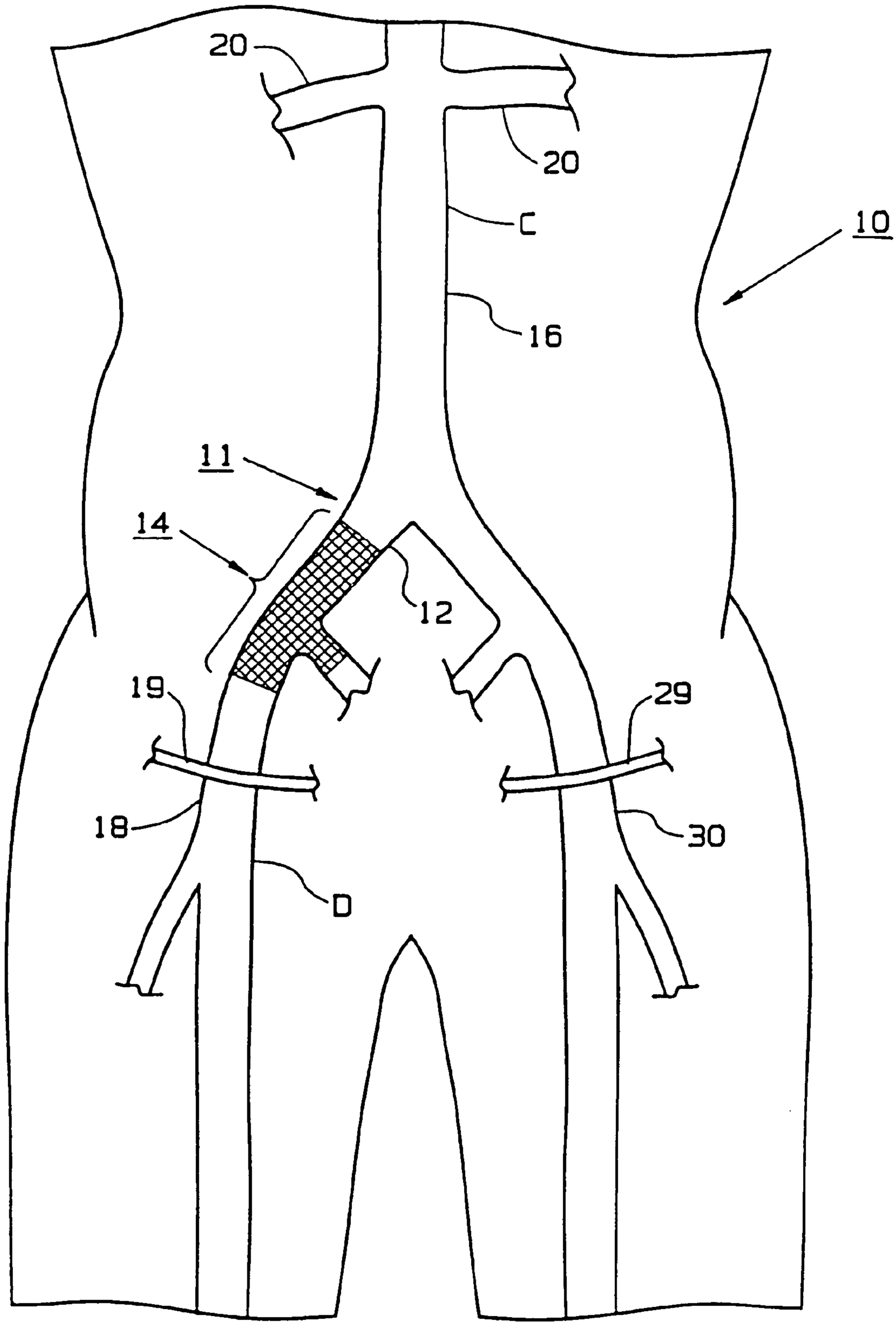
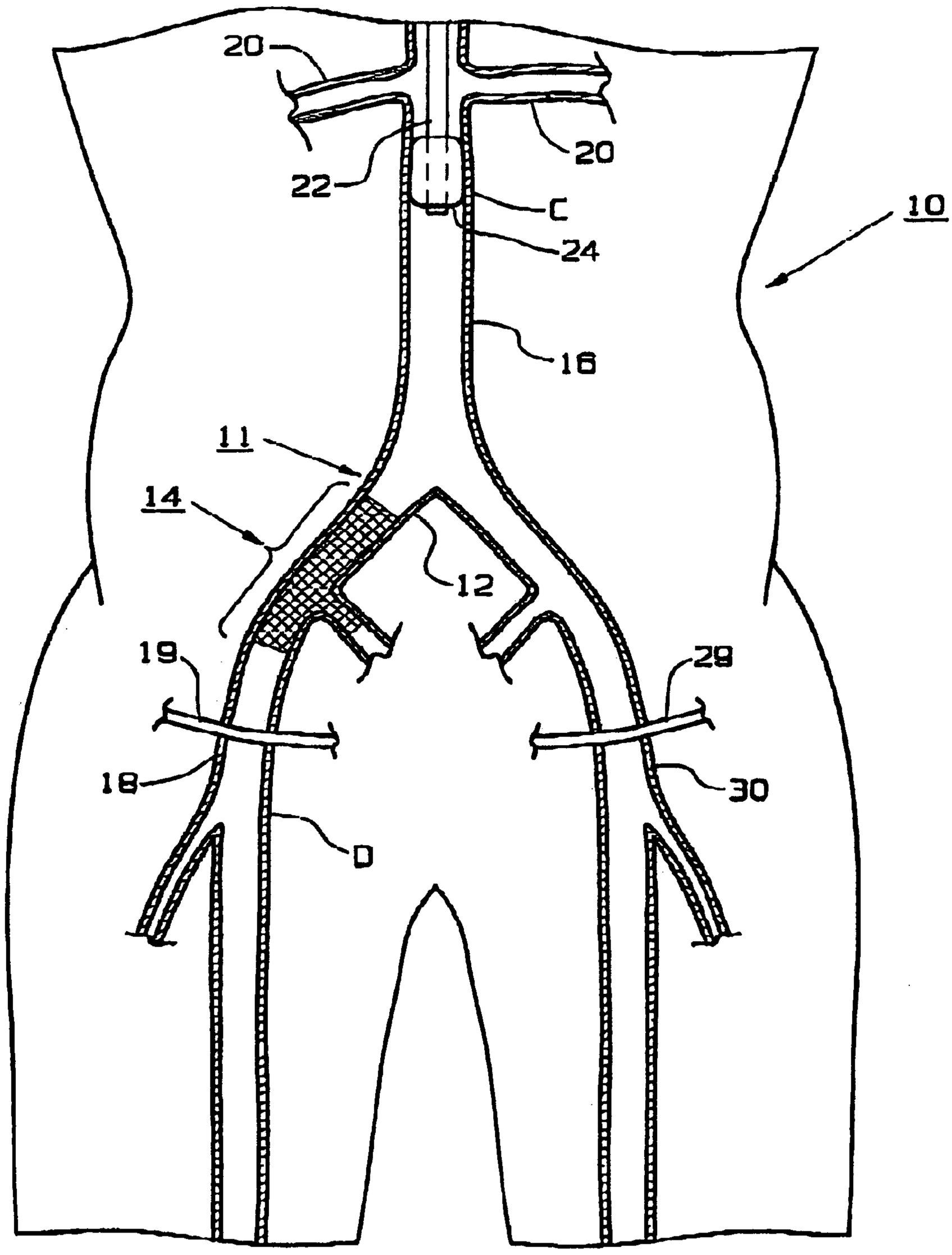


FIG. 2



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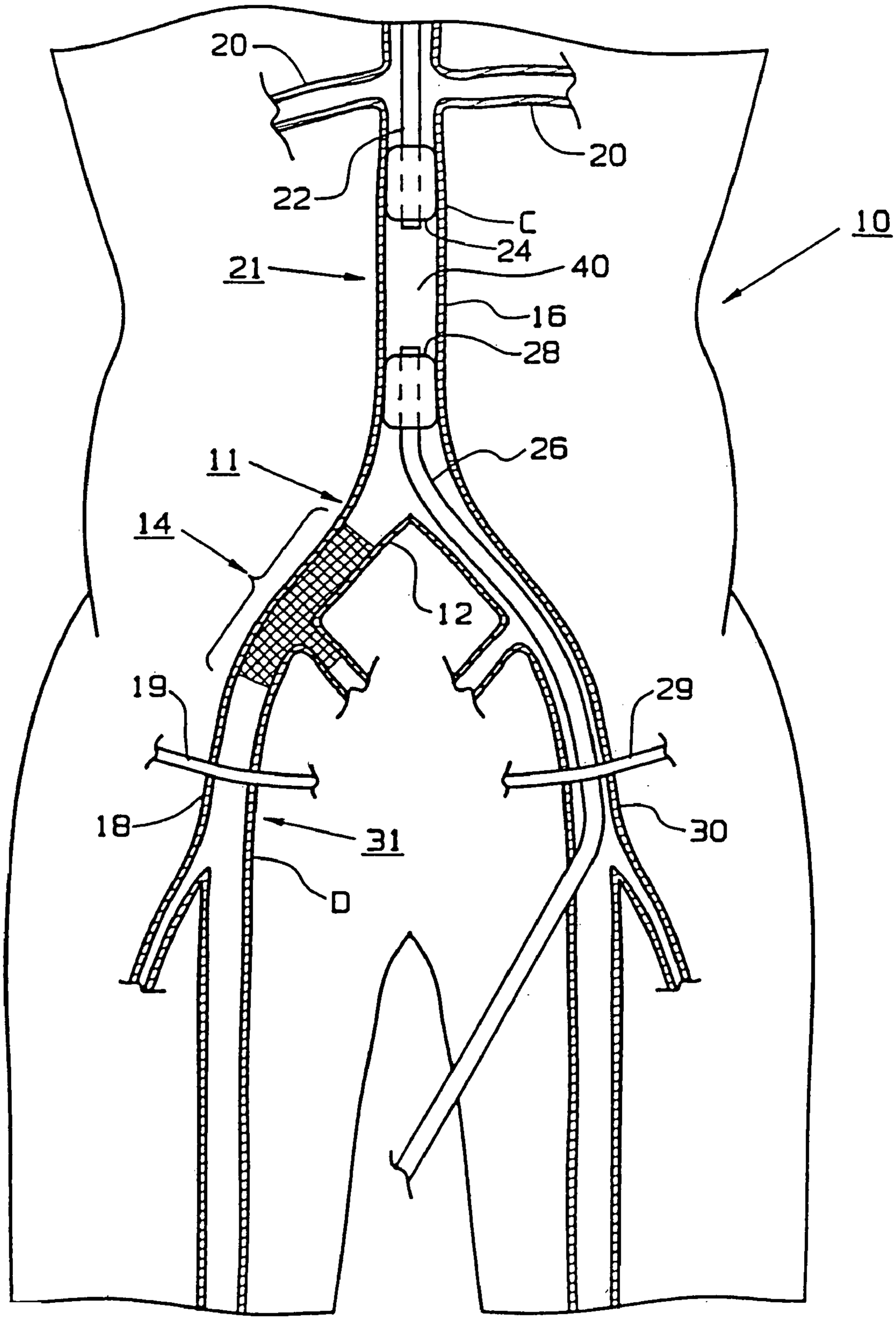

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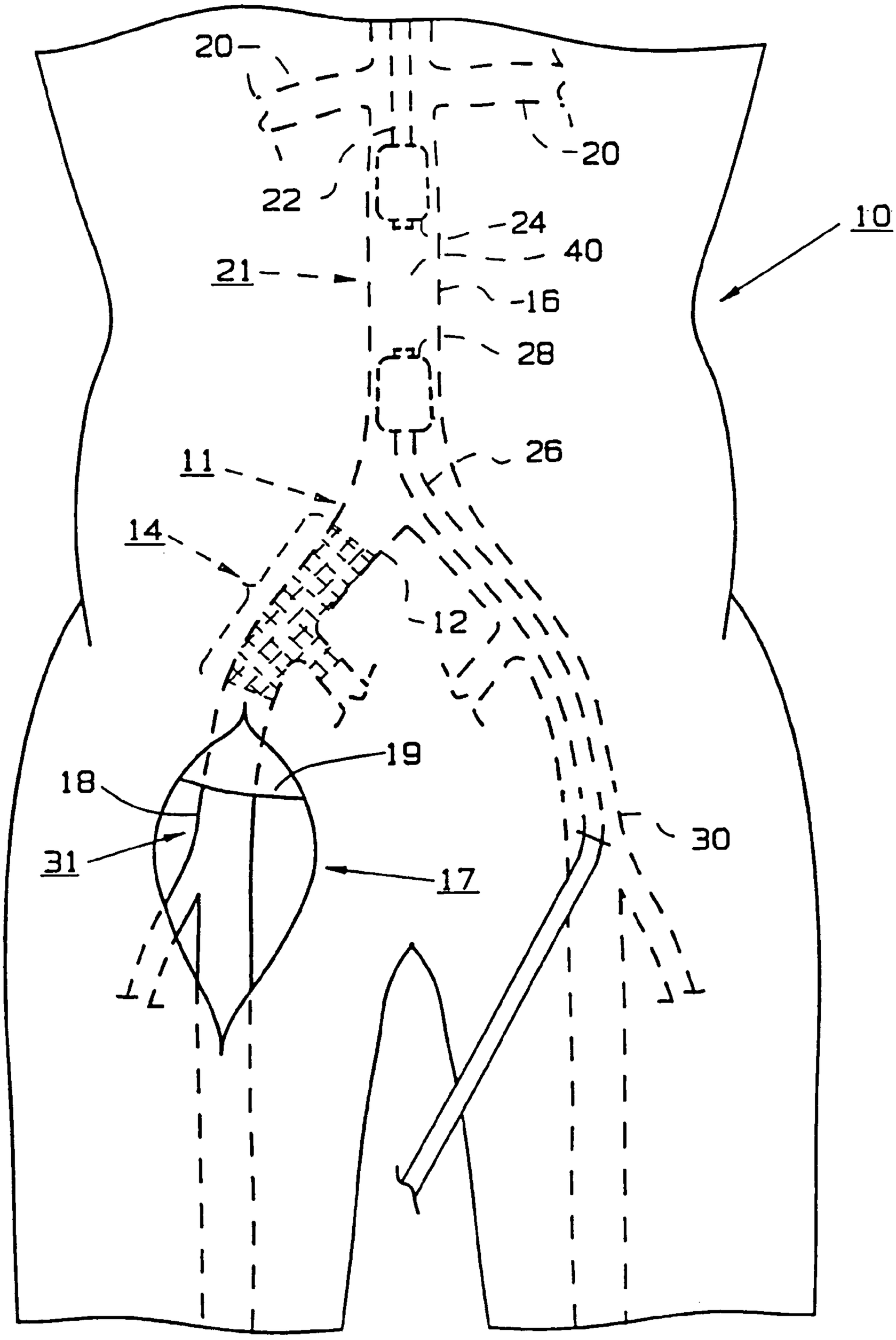


Fig. 5

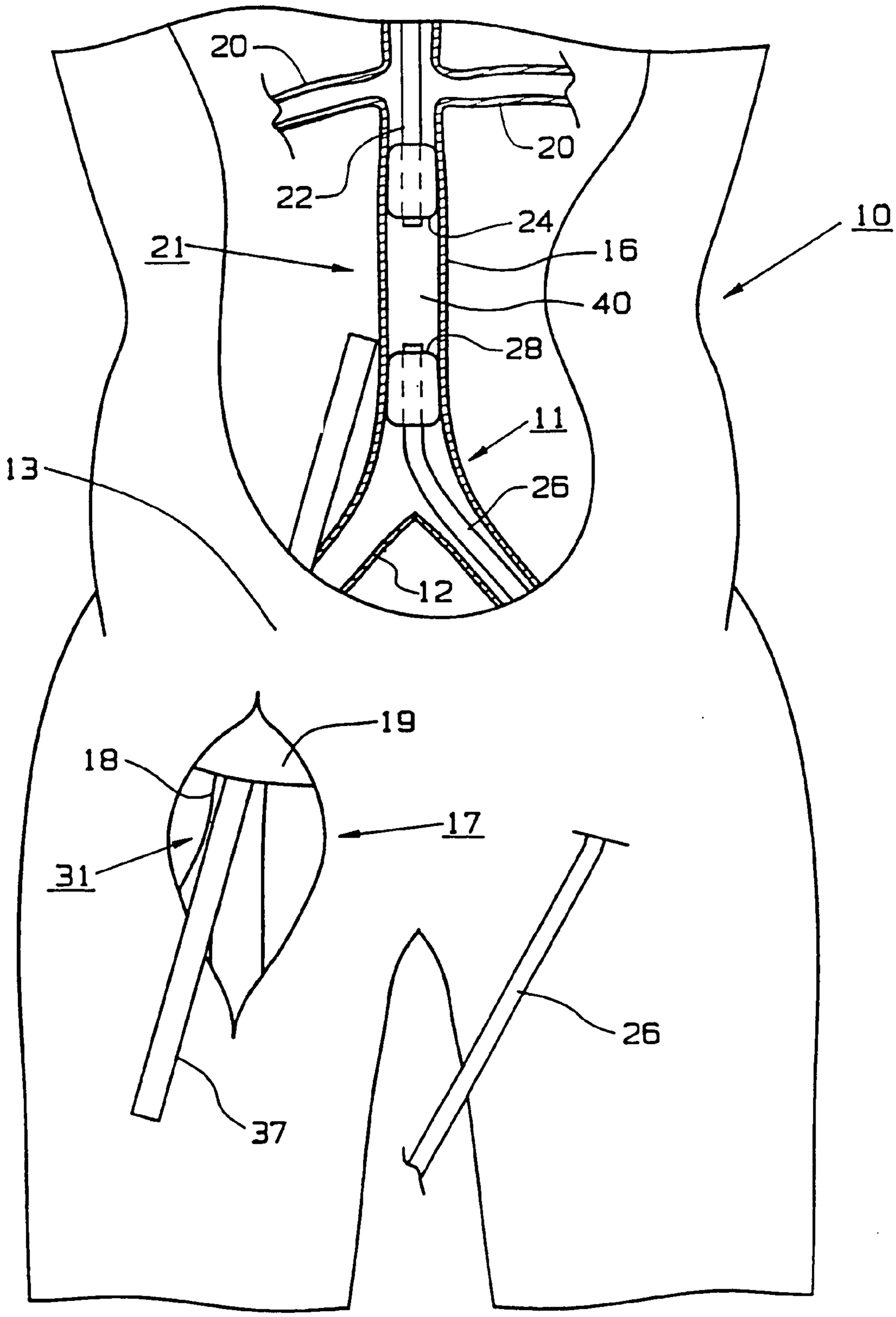


FIG. 6

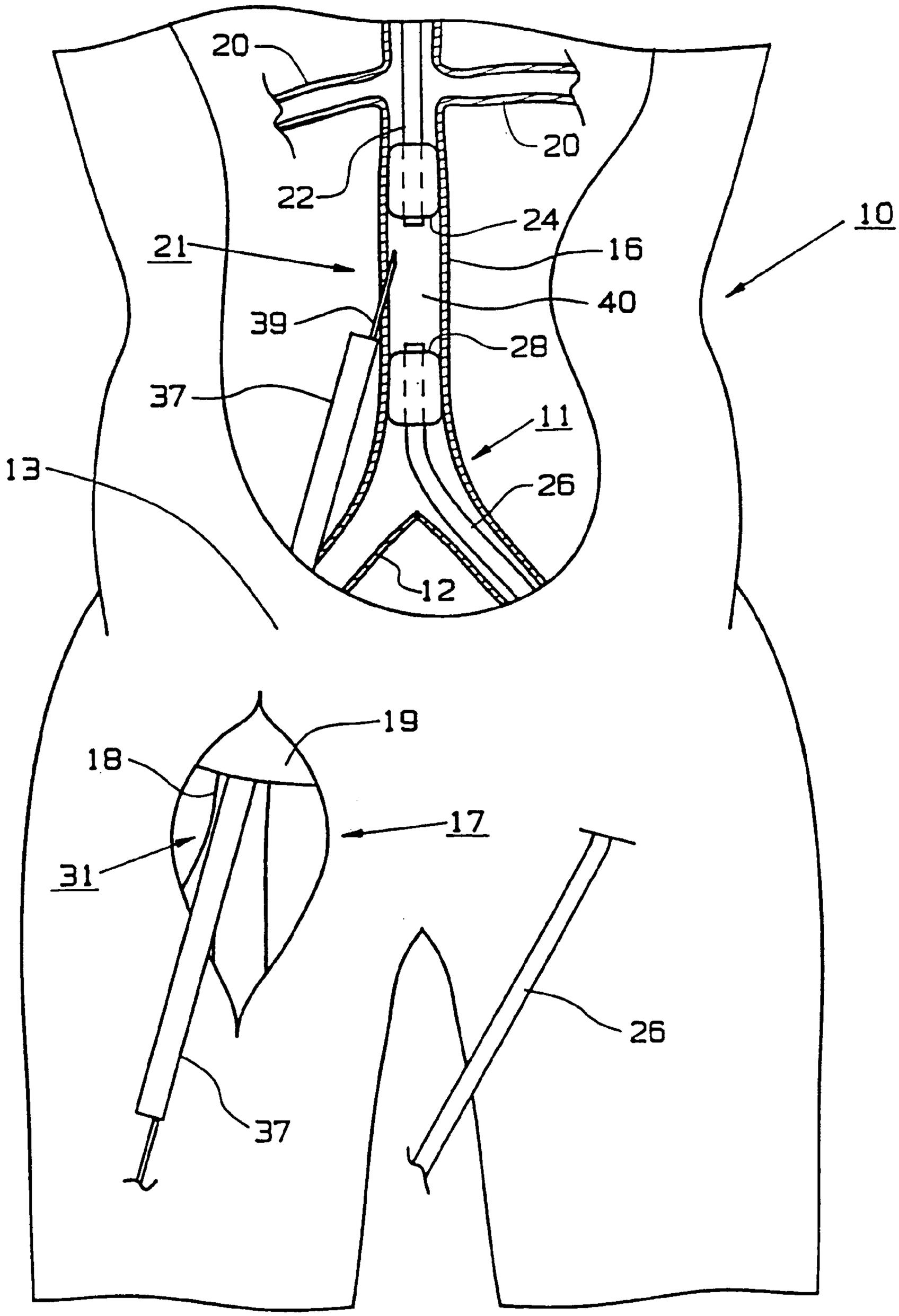
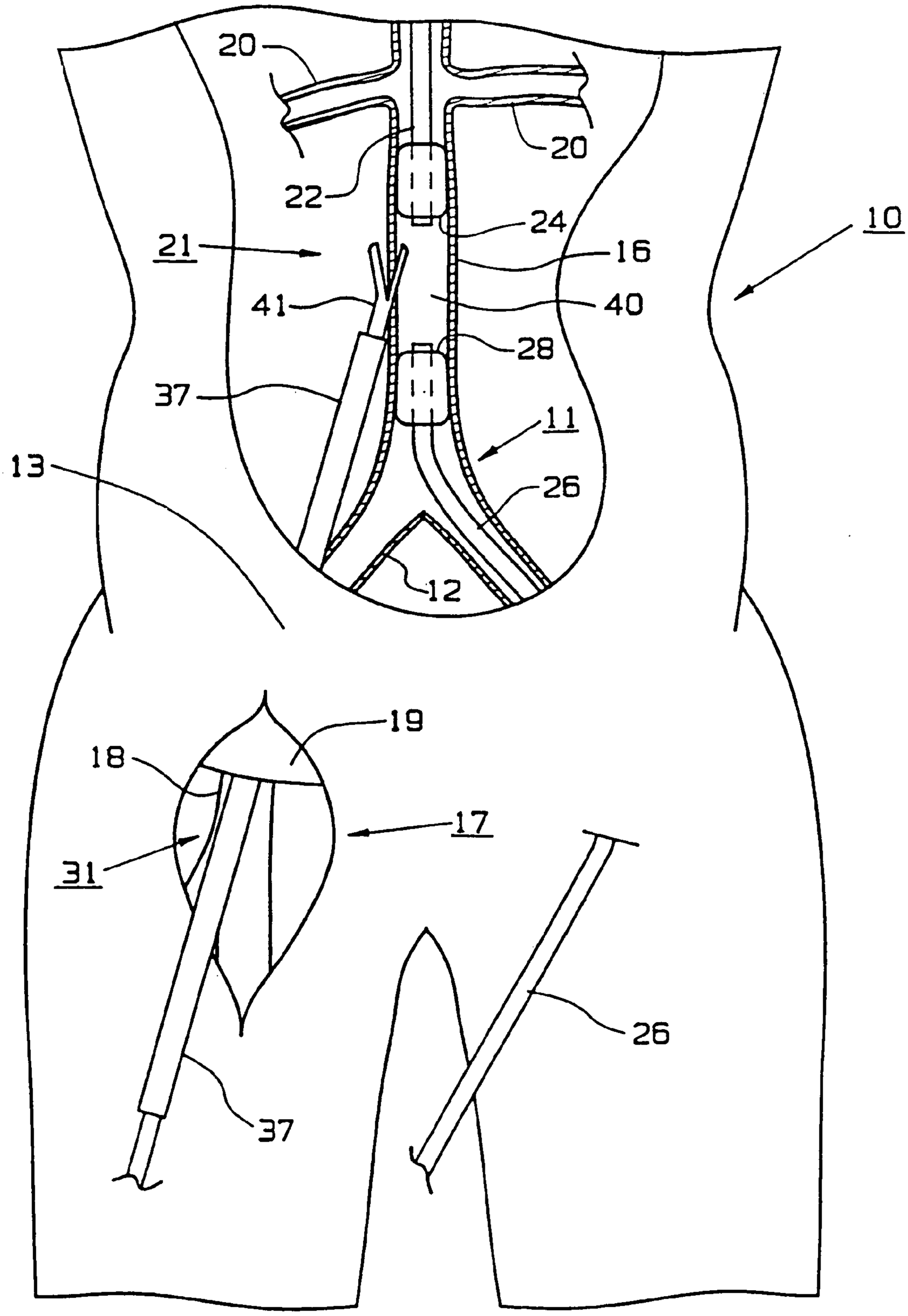


Fig. 7



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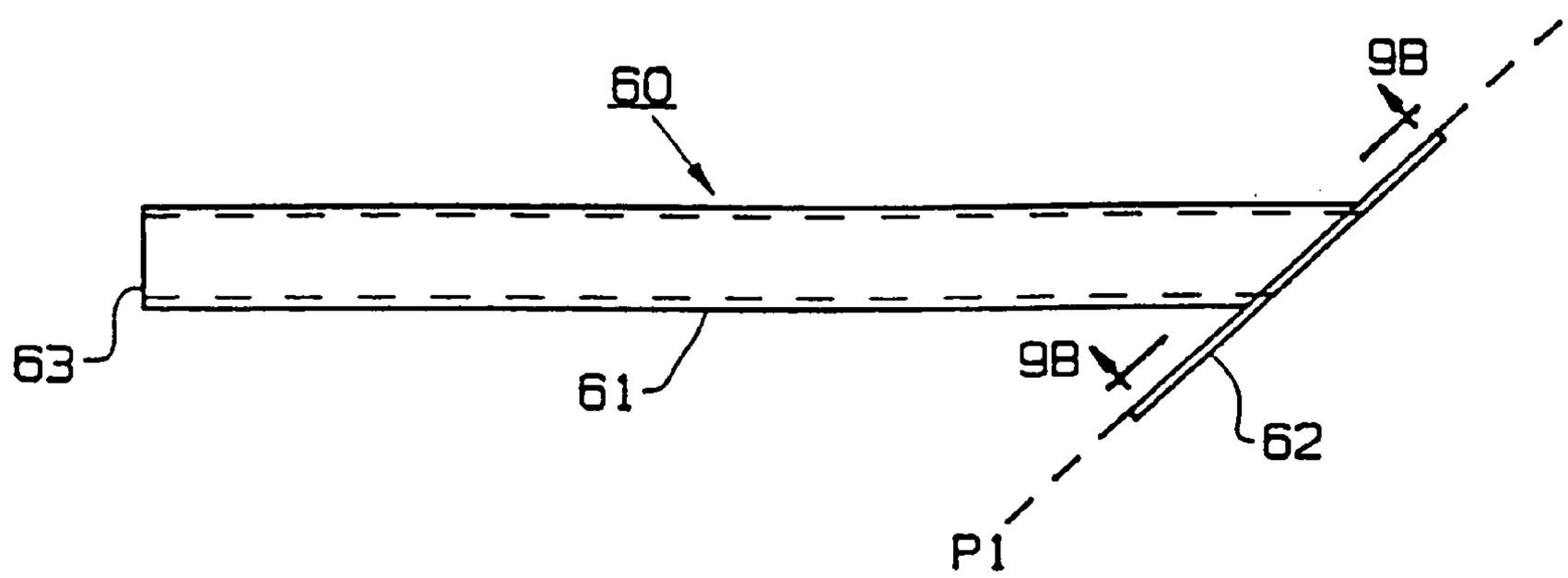


FIG. 9A

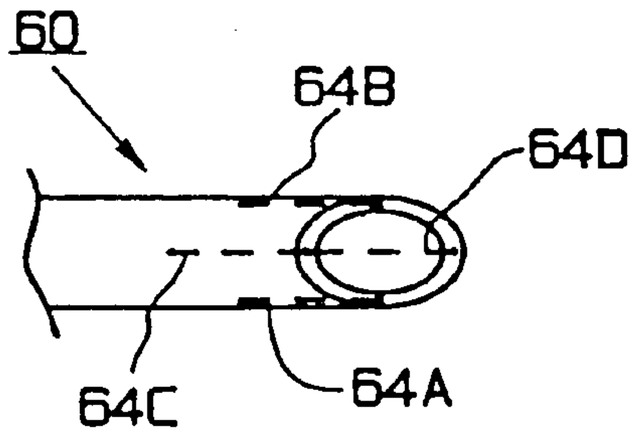


FIG. 9B

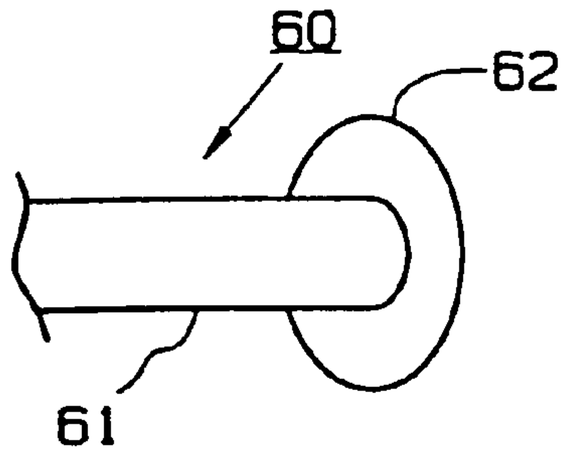


FIG. 9C

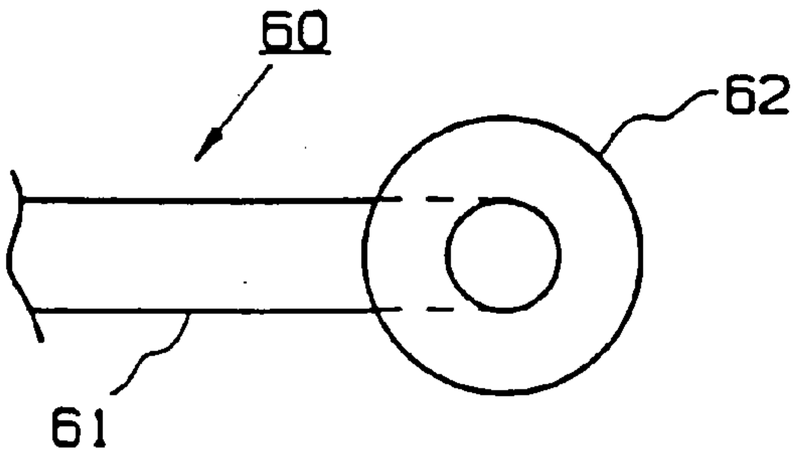


FIG. 9D

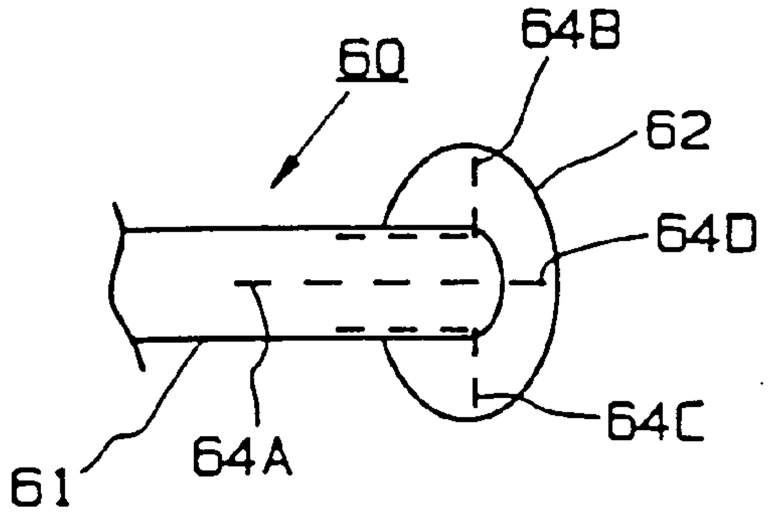


FIG. 9E

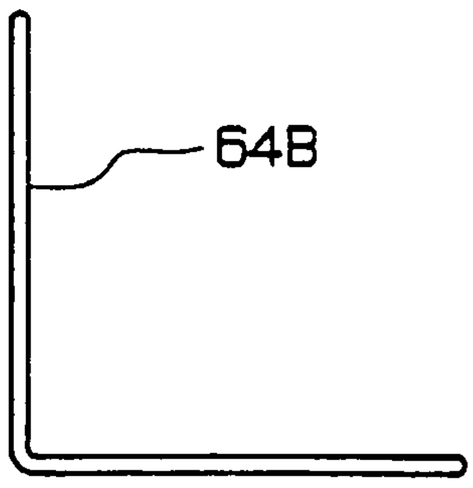


FIG. 9F

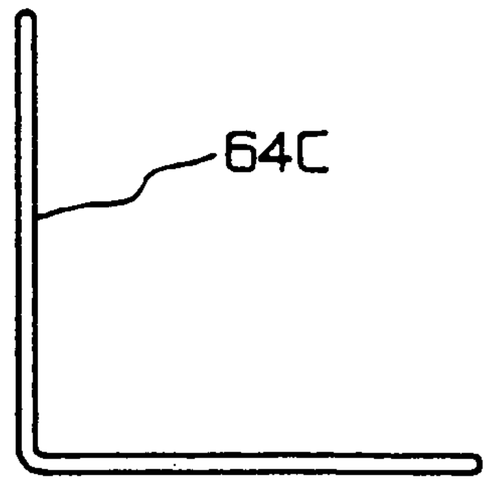


FIG. 9G

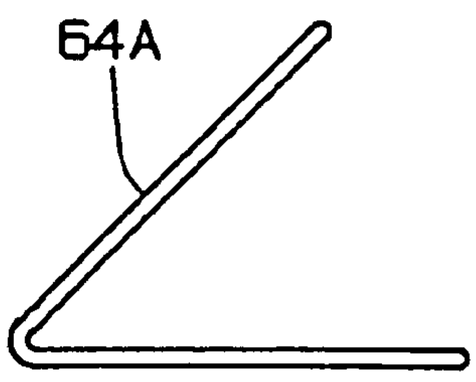


FIG. 9H

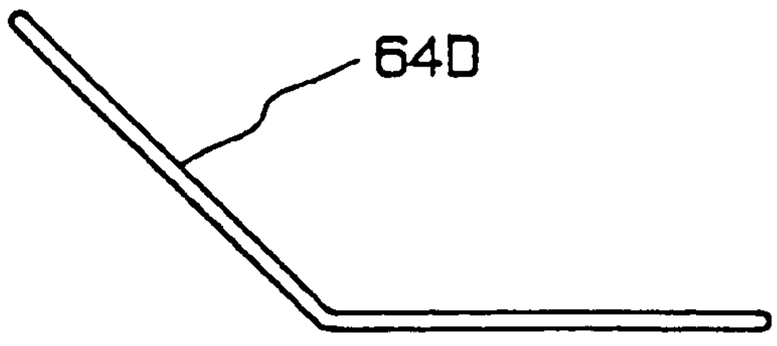


FIG. 9I

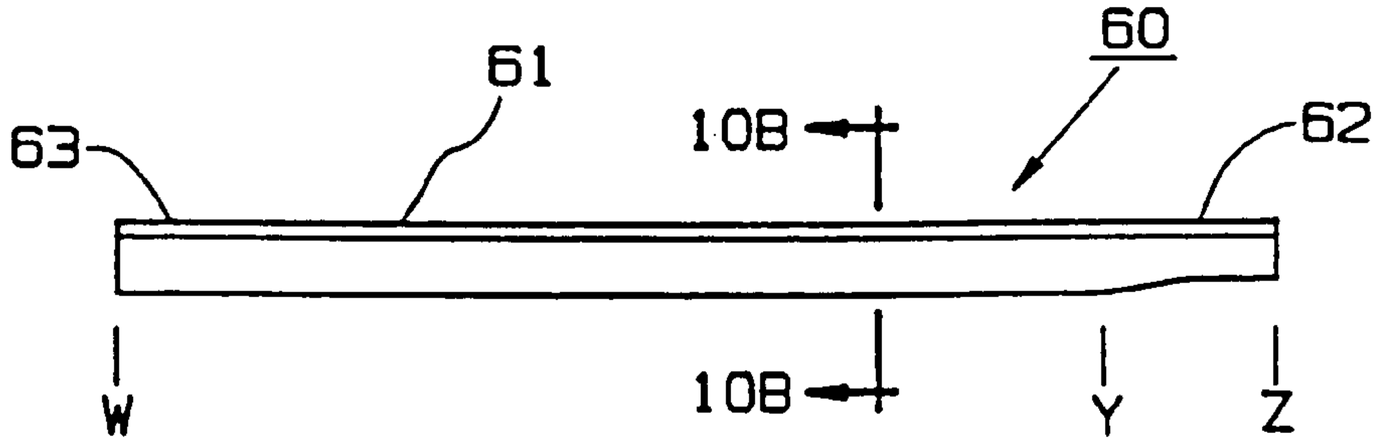


FIG. 10A

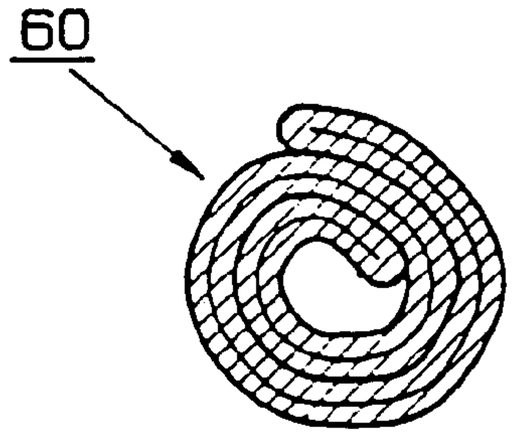


FIG. 10B

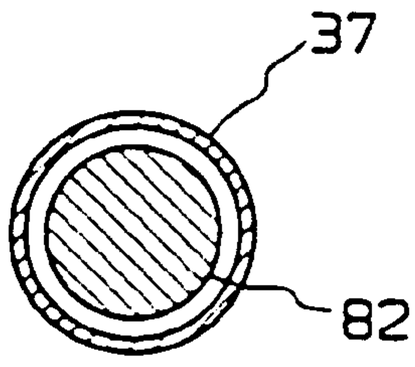


FIG. 11B

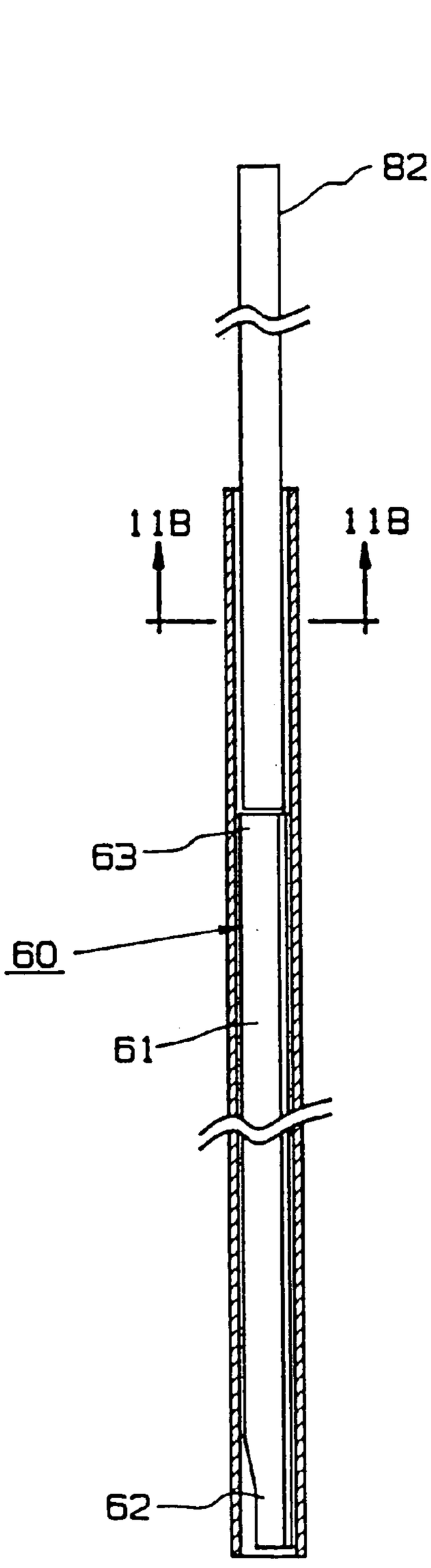


FIG. 11A

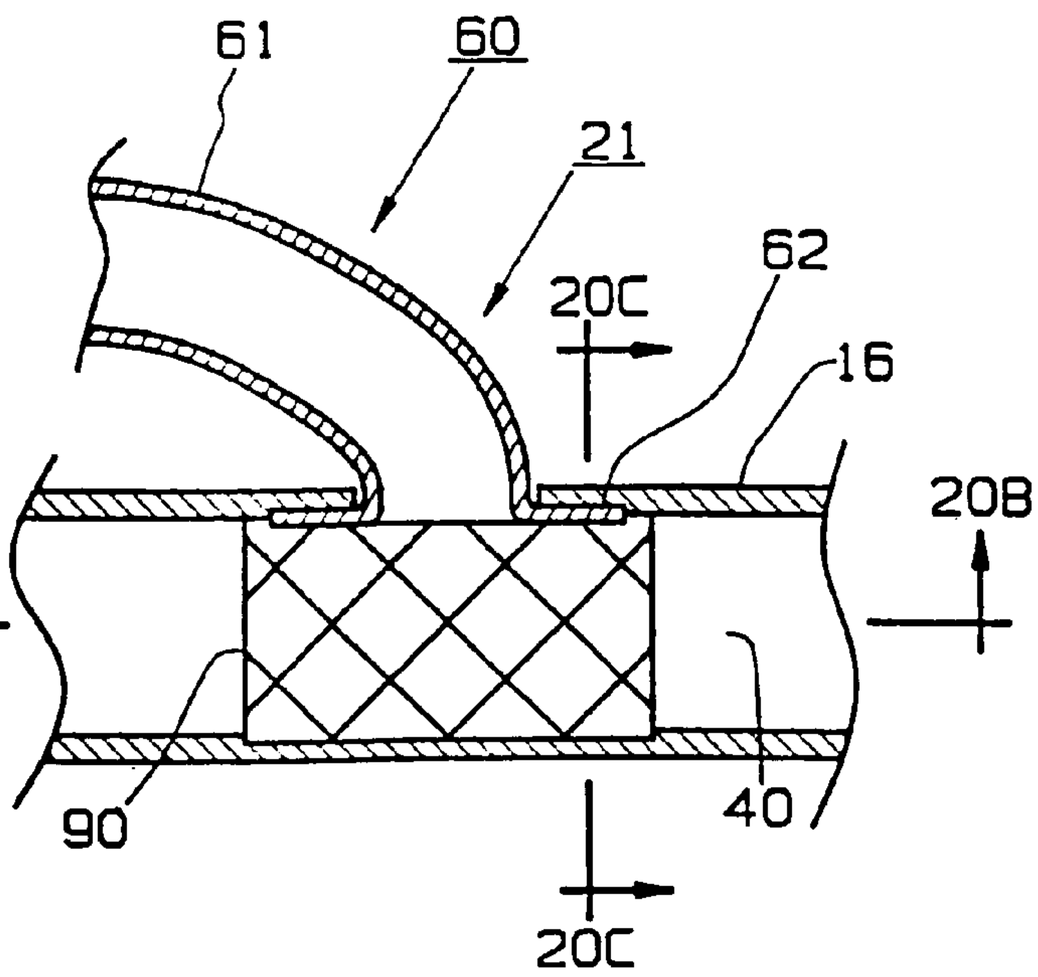
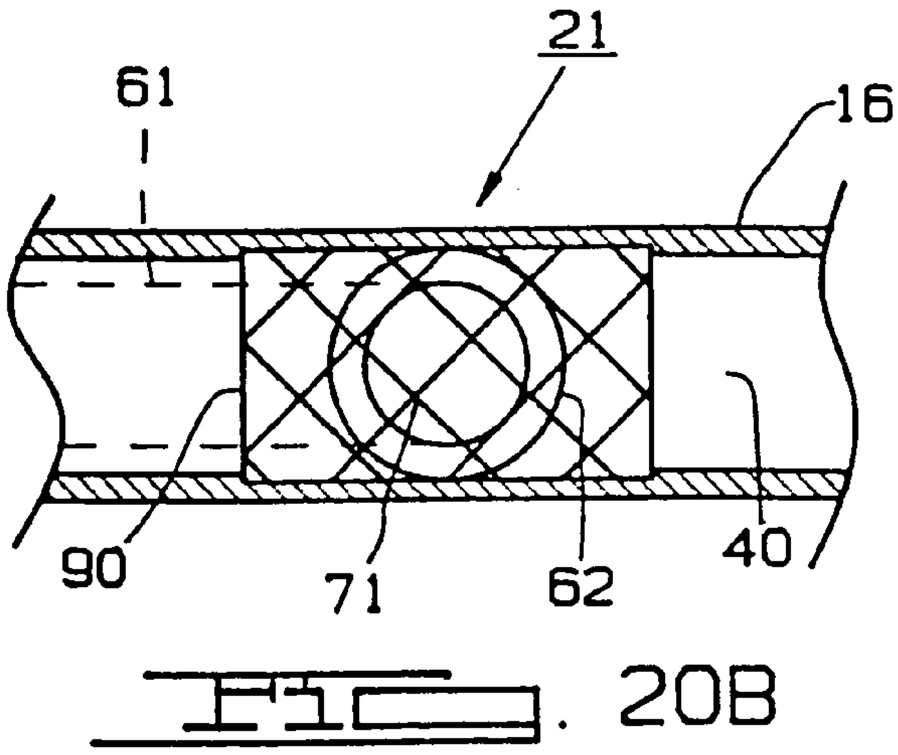


FIG. 20A



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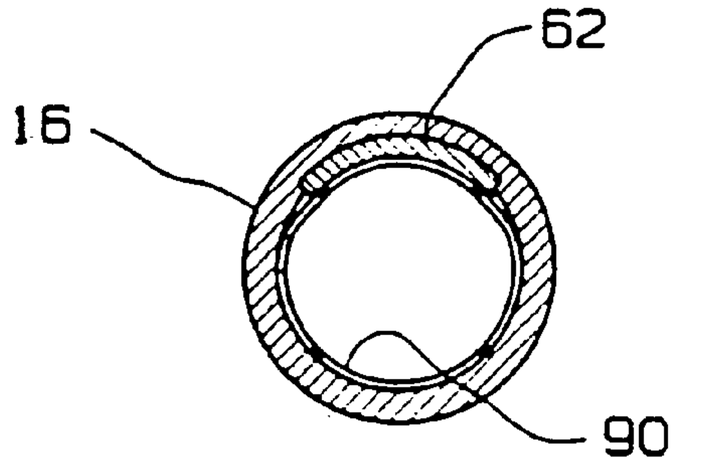

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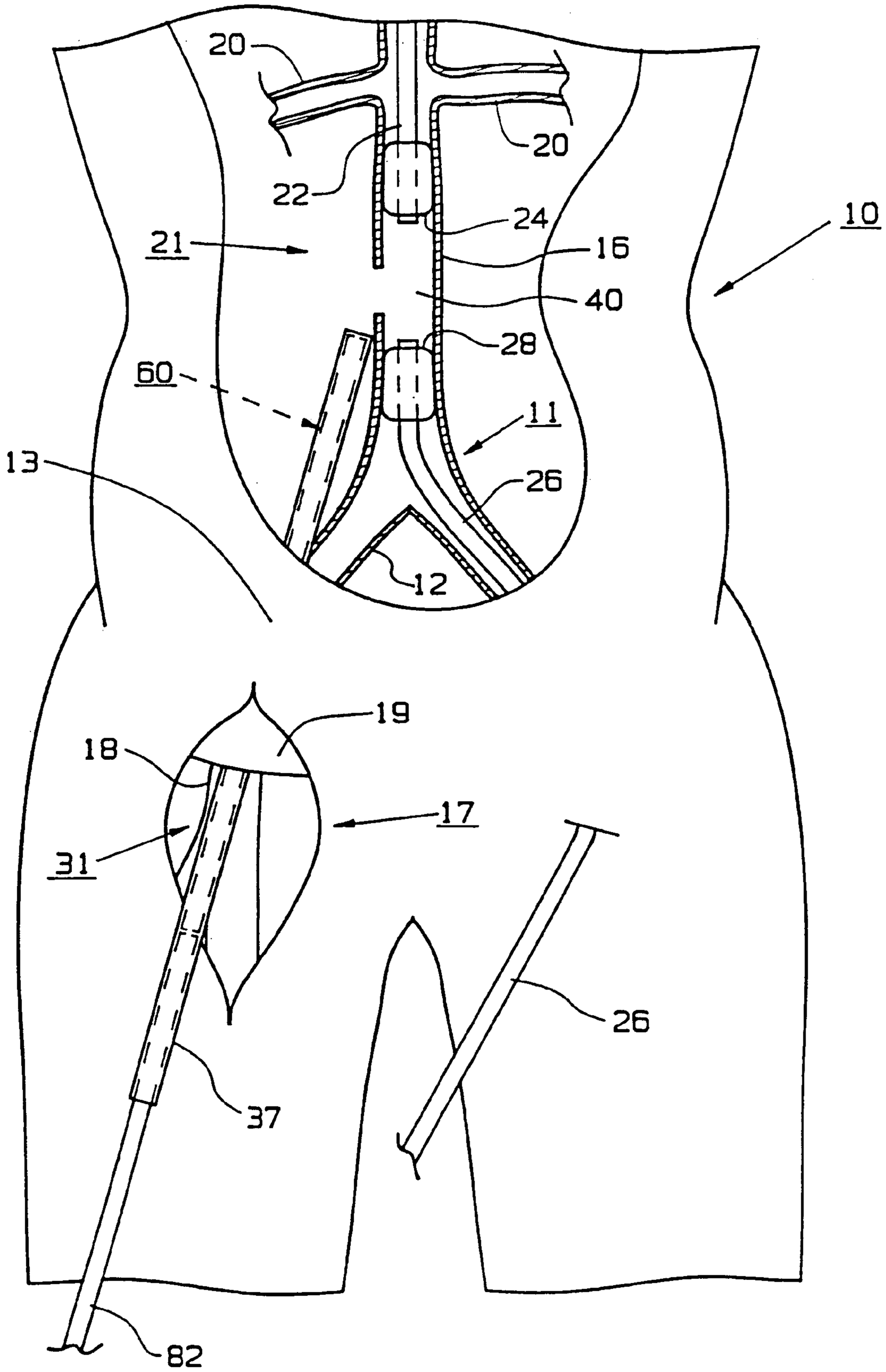

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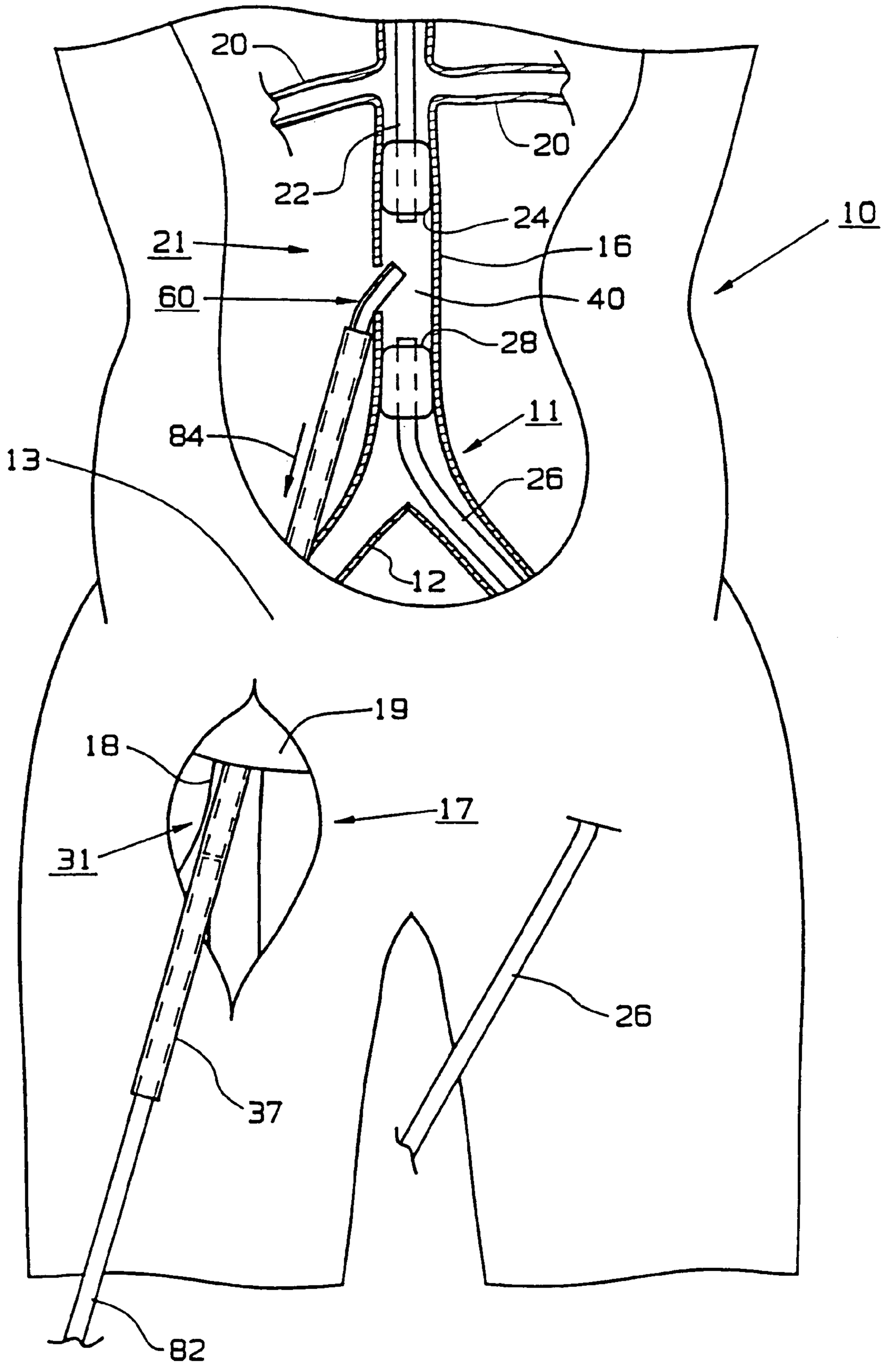
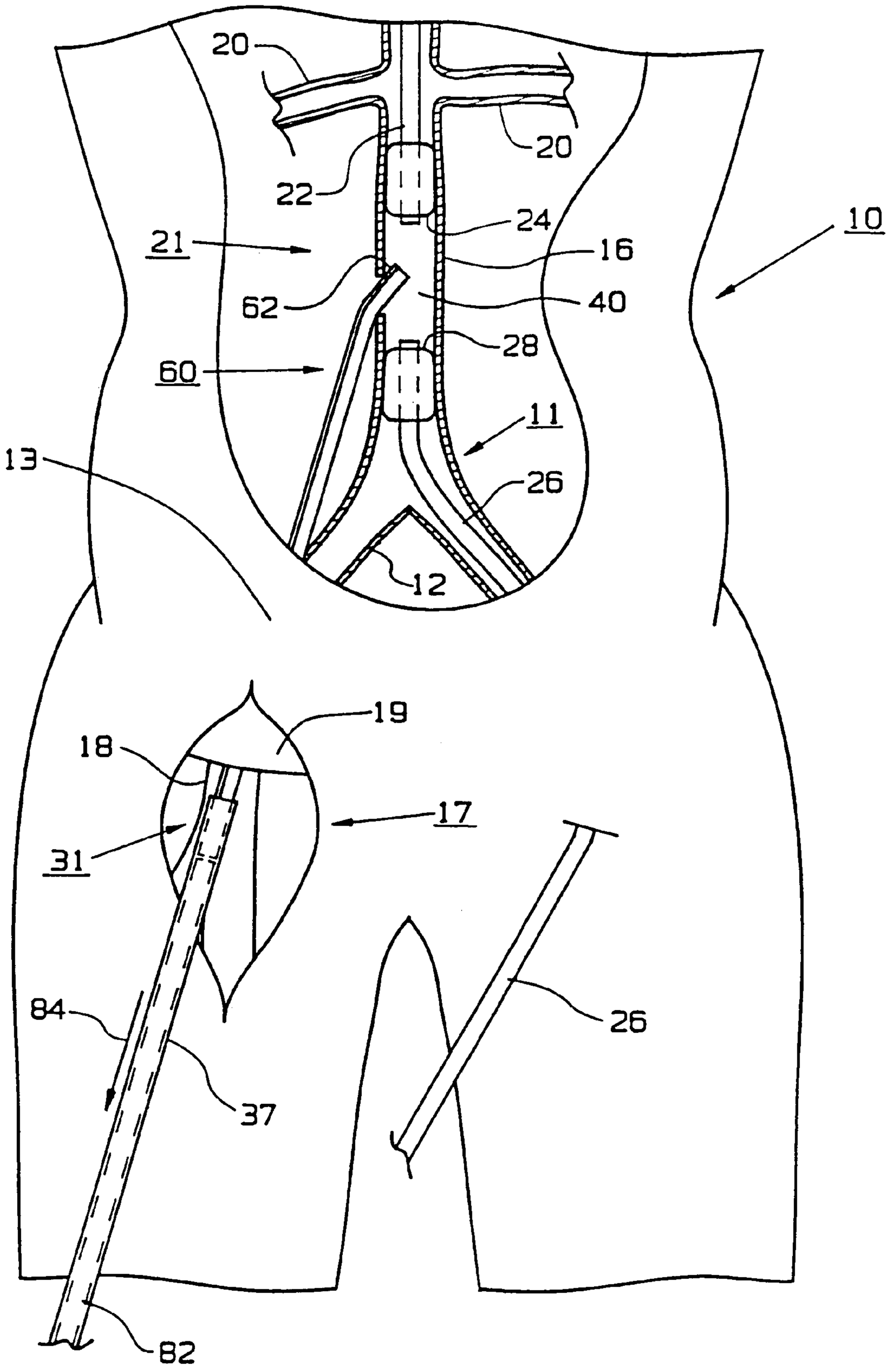


FIG. 13



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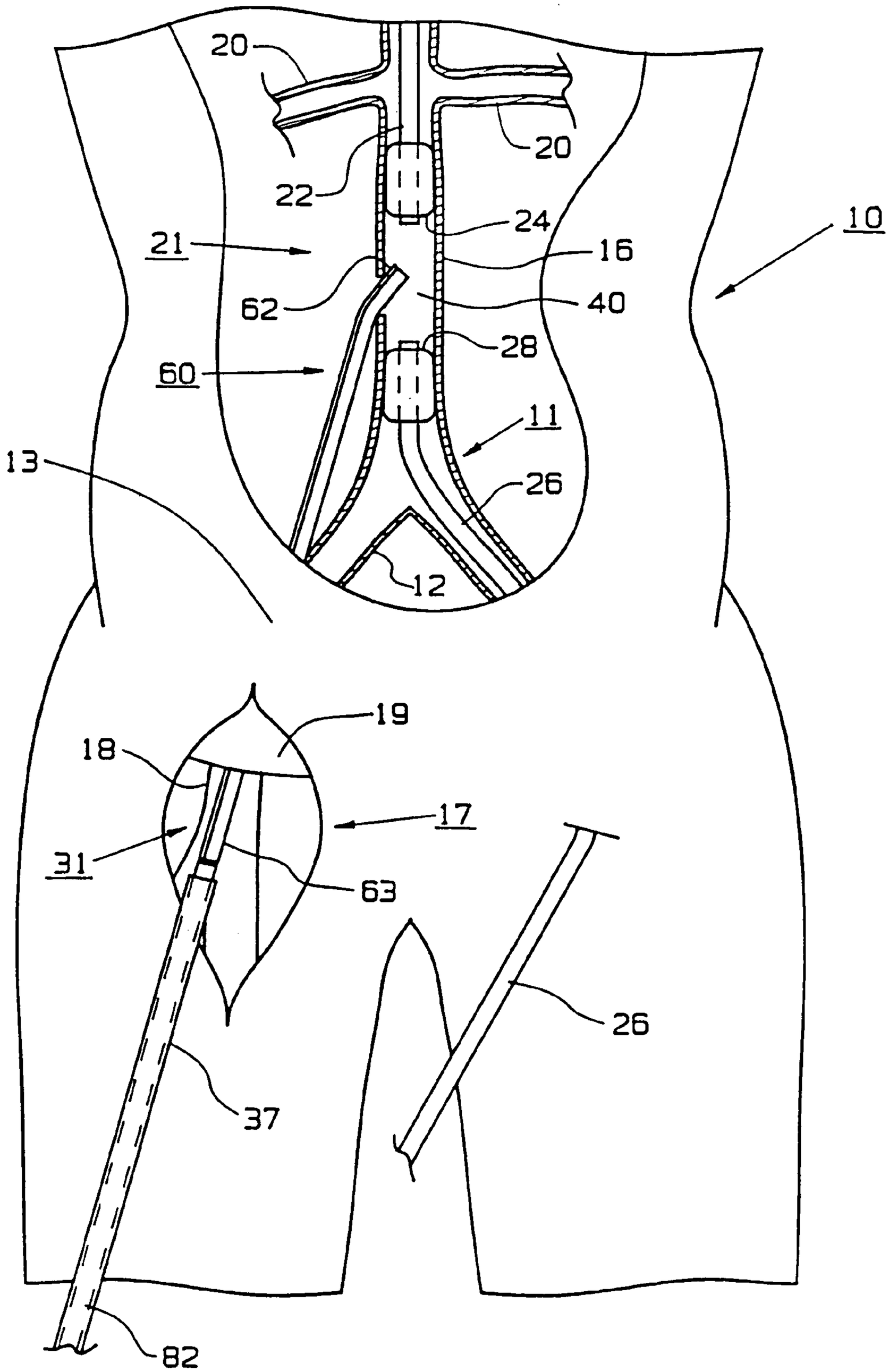


Fig. 15

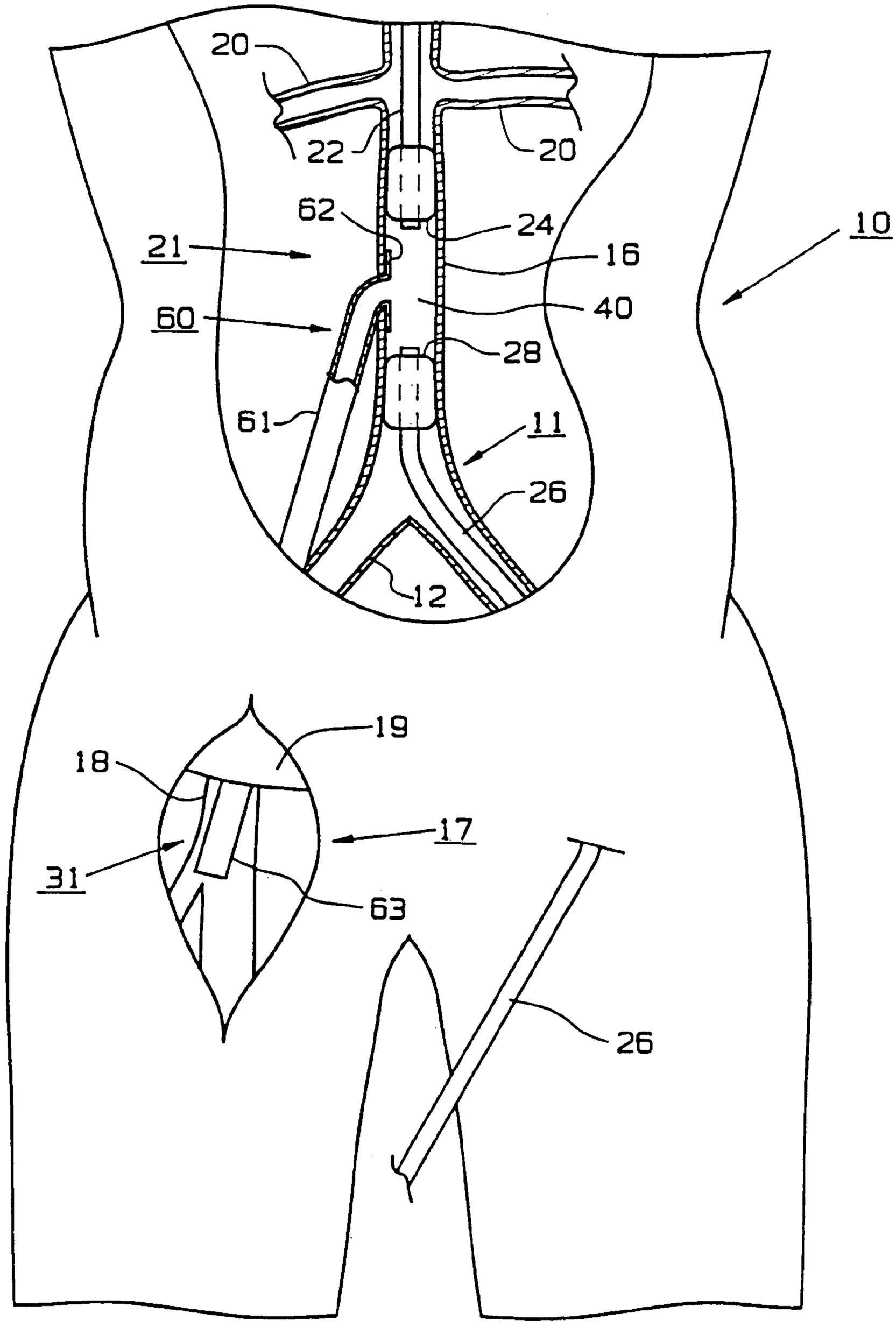
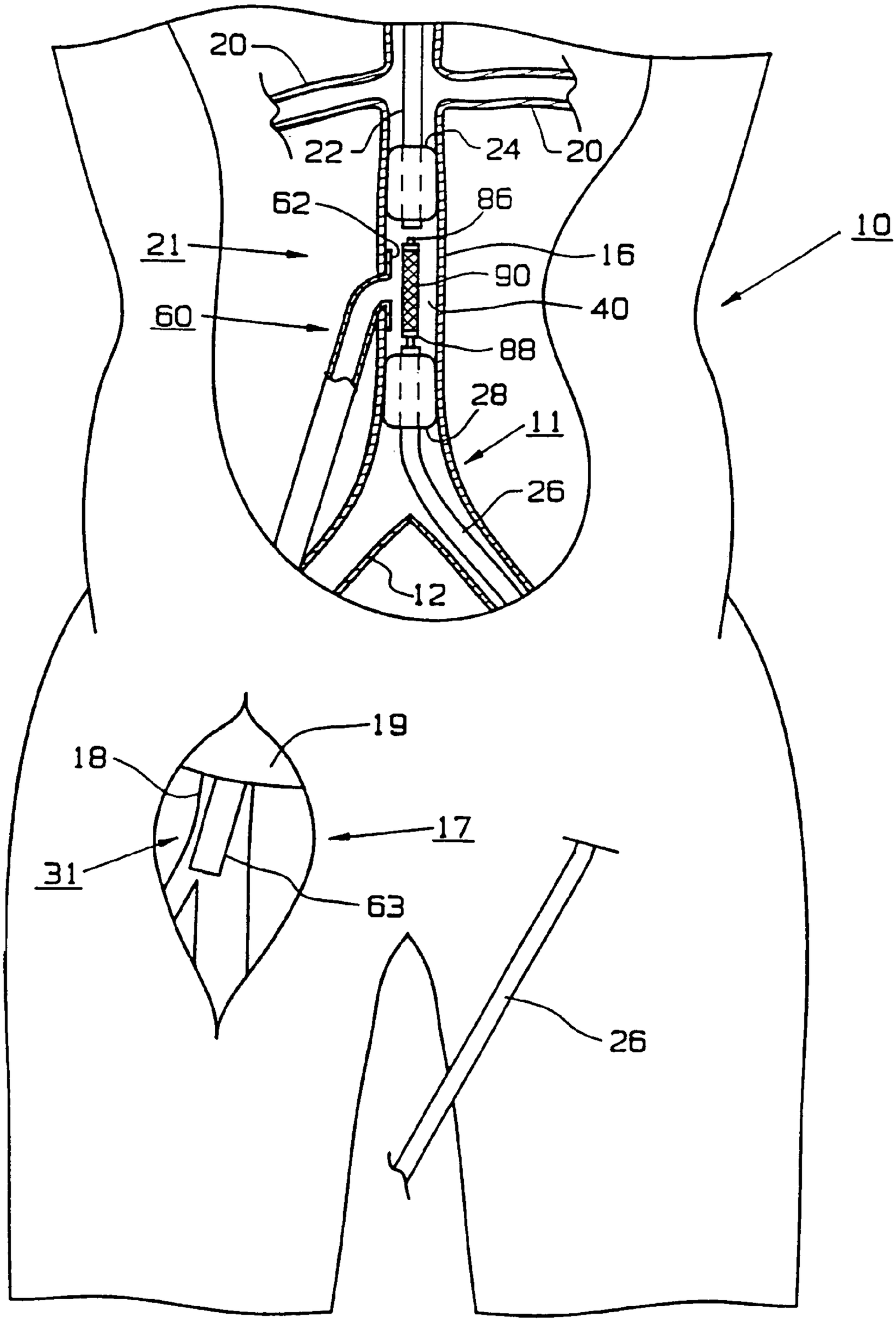


FIG. 16



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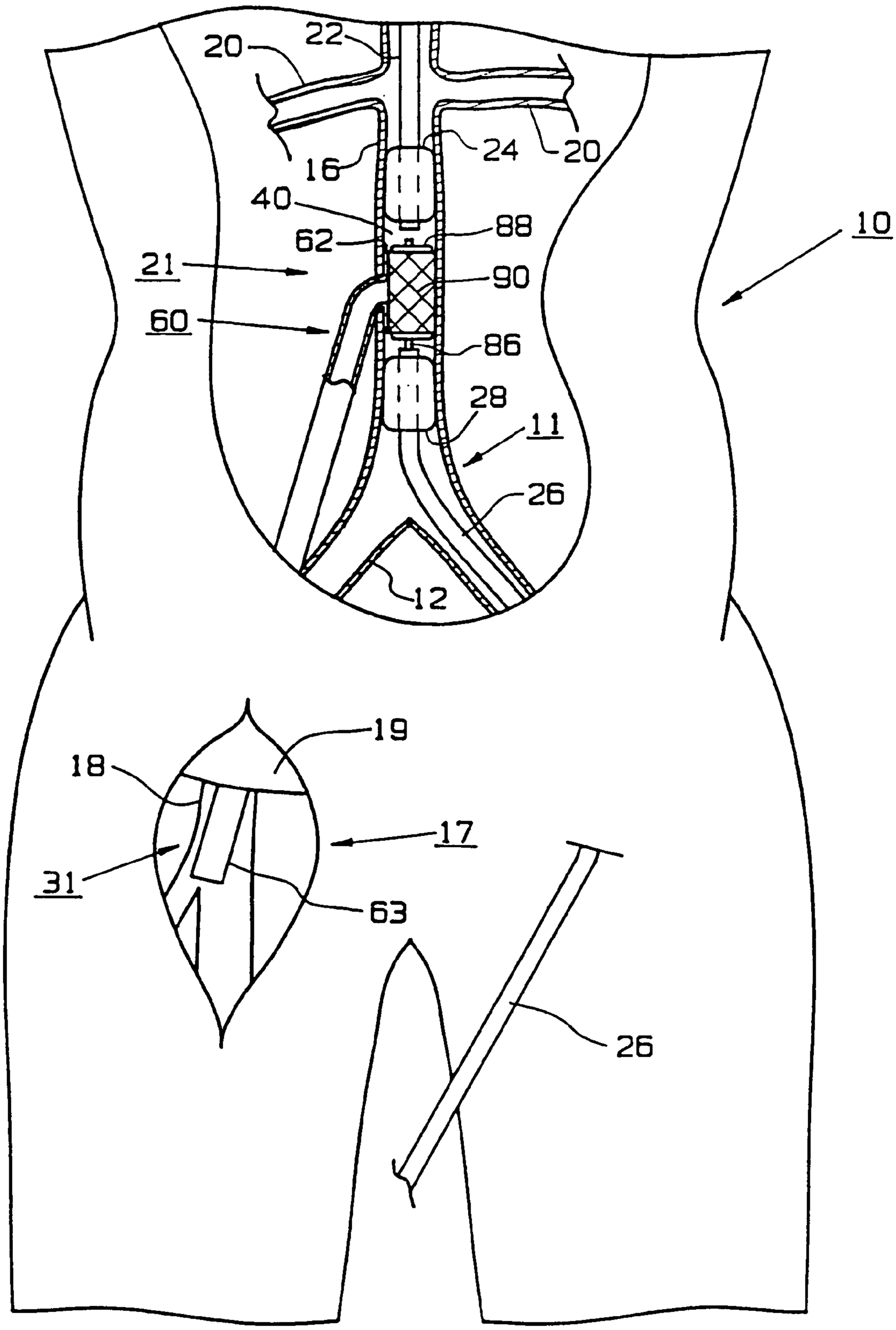


Fig. 18

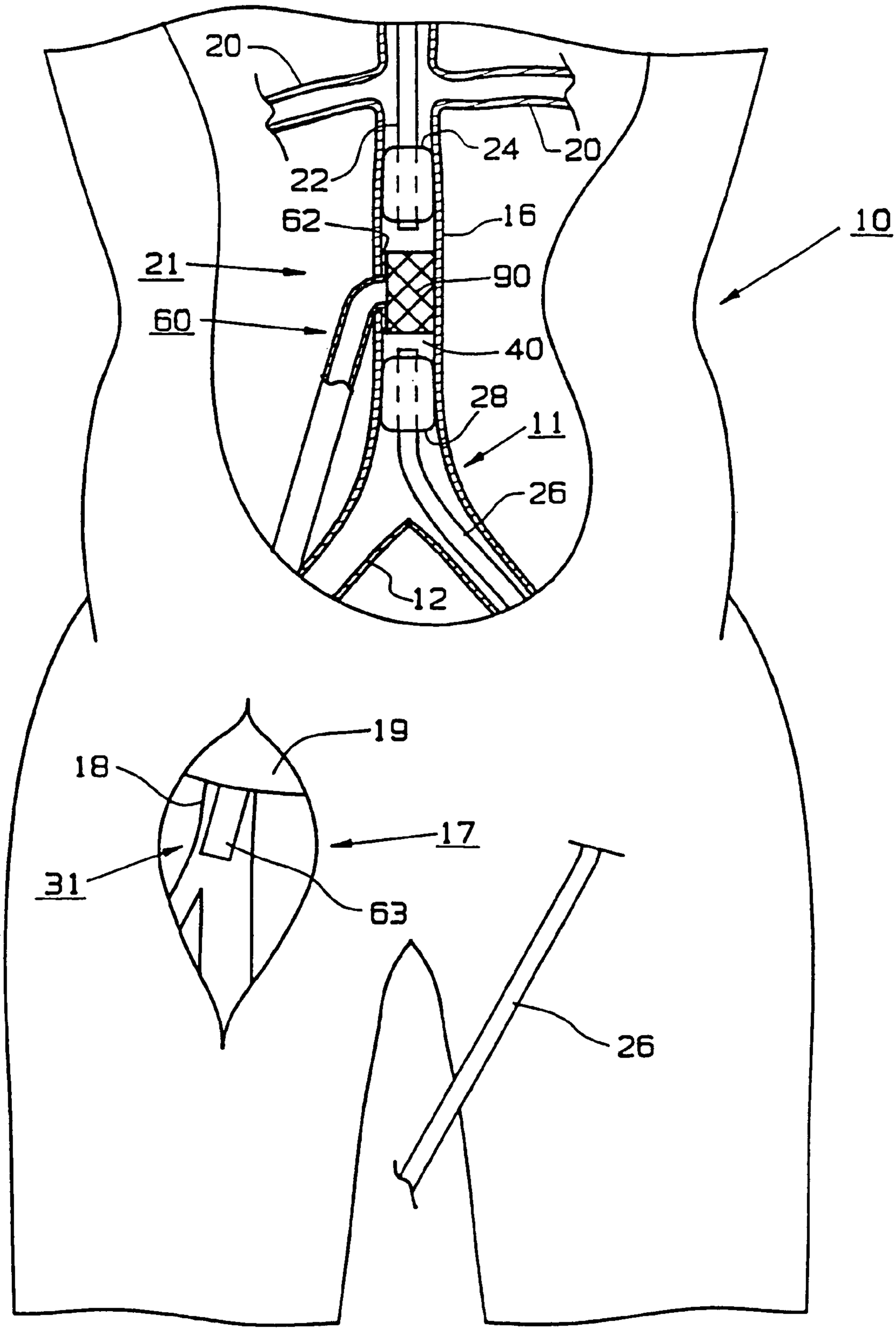
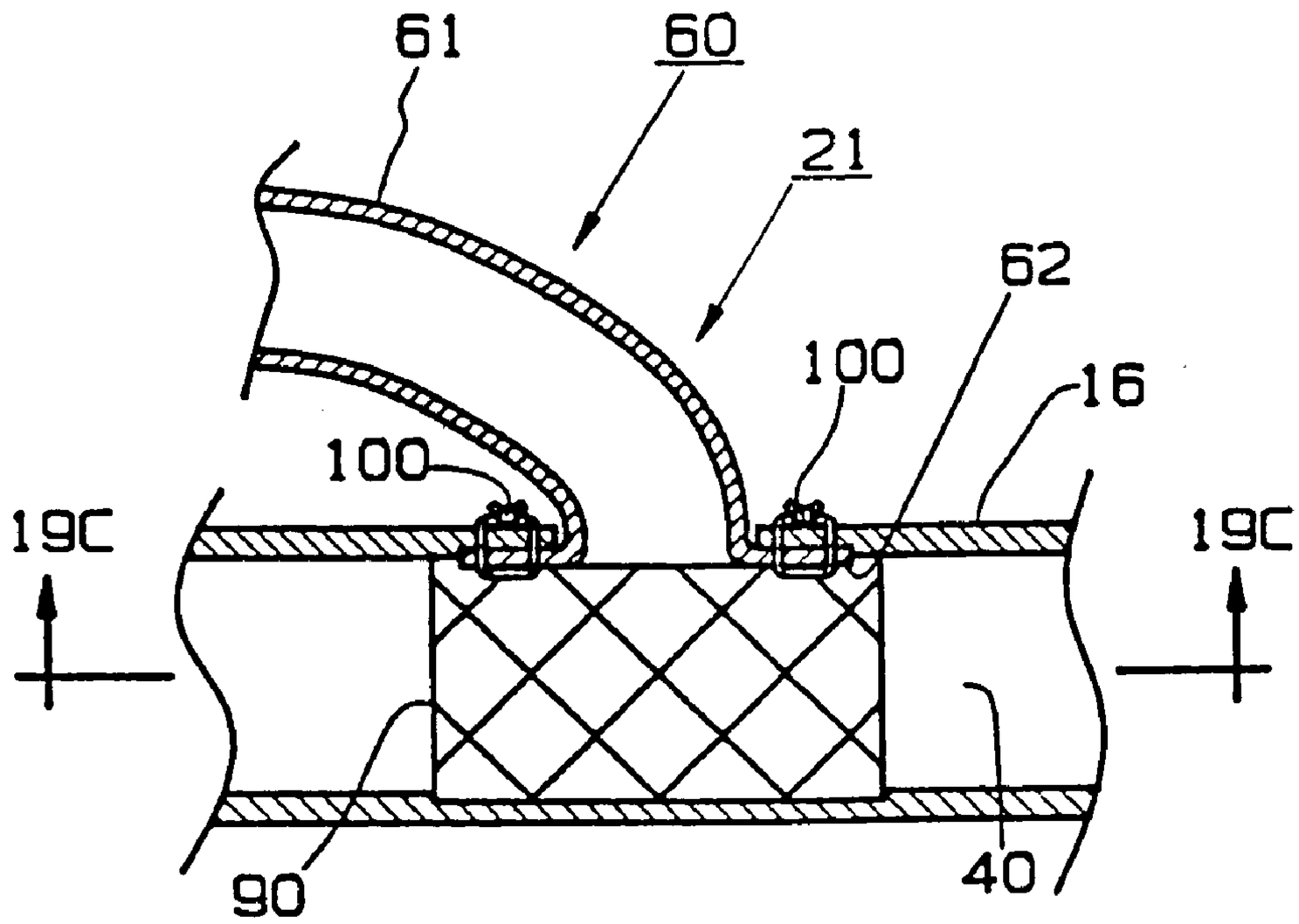


FIG. 19A



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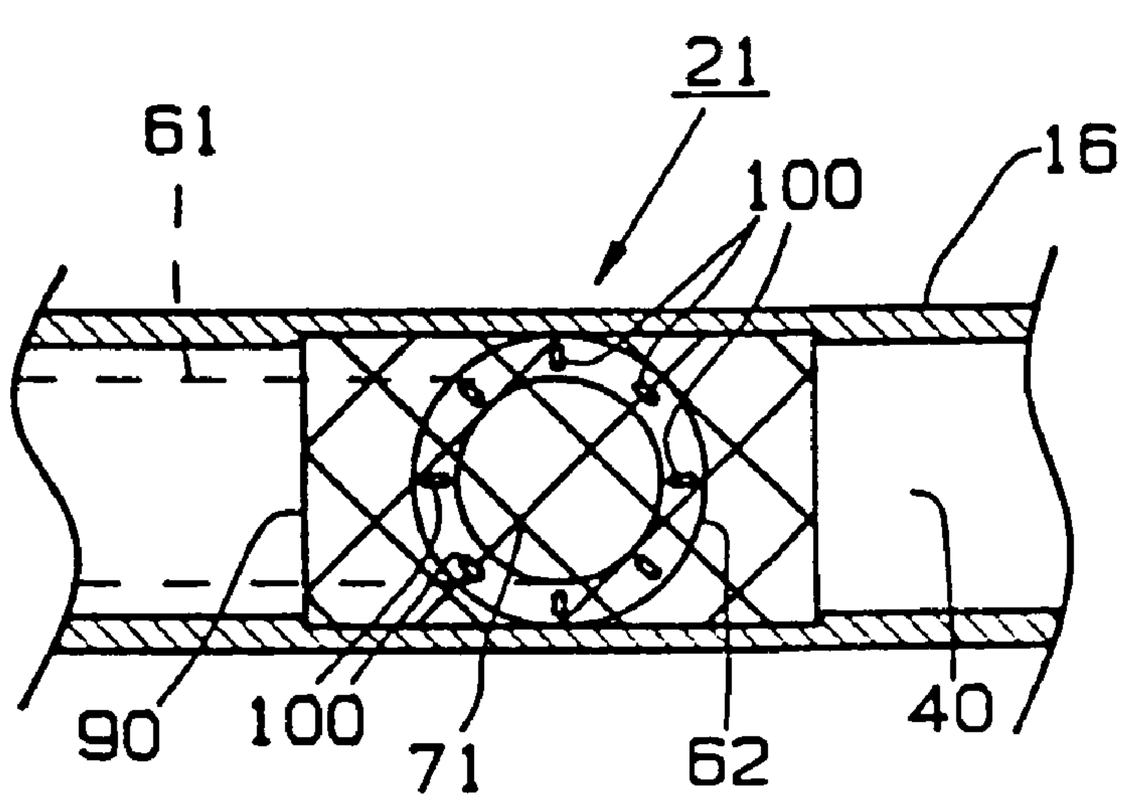

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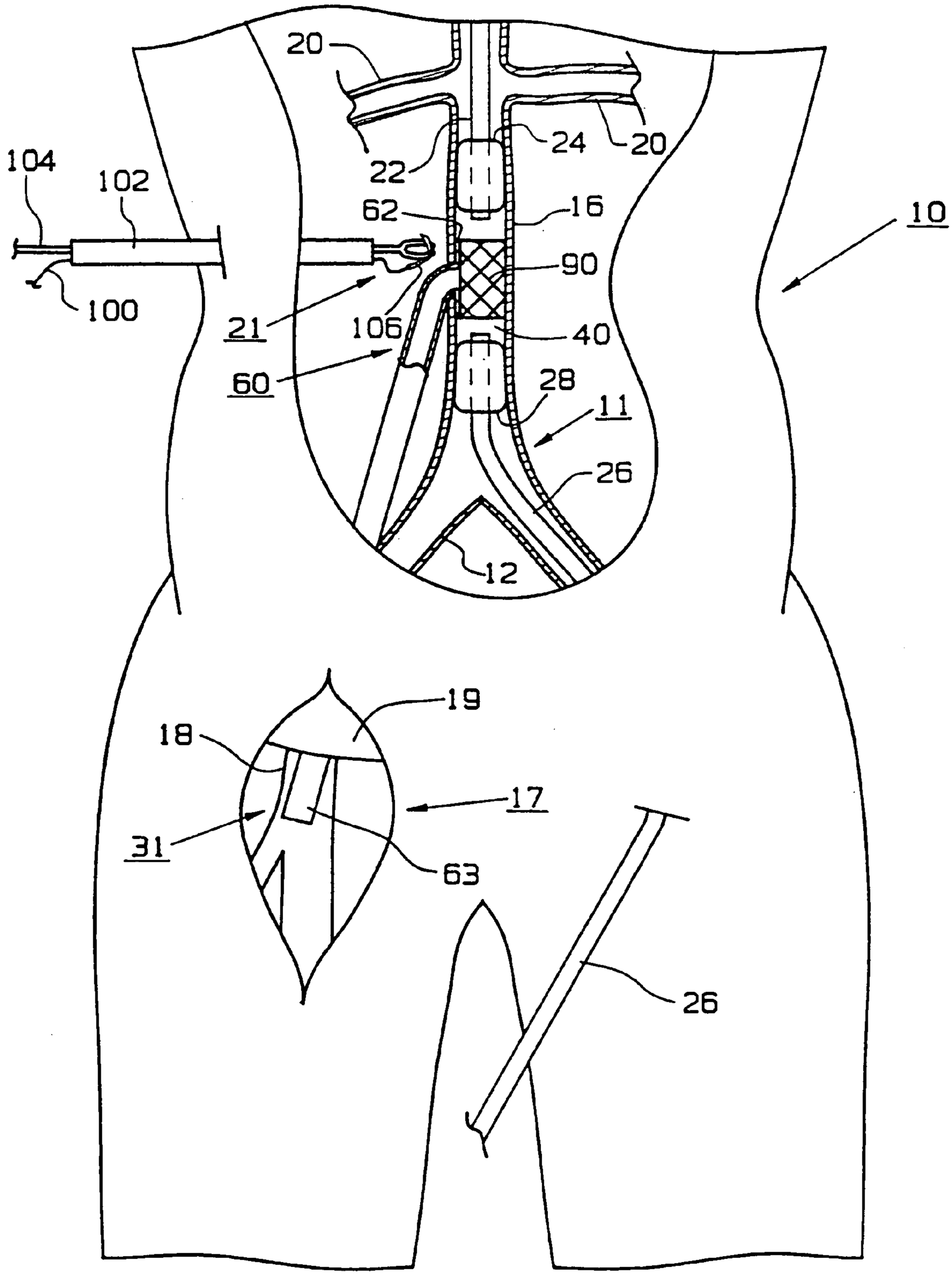
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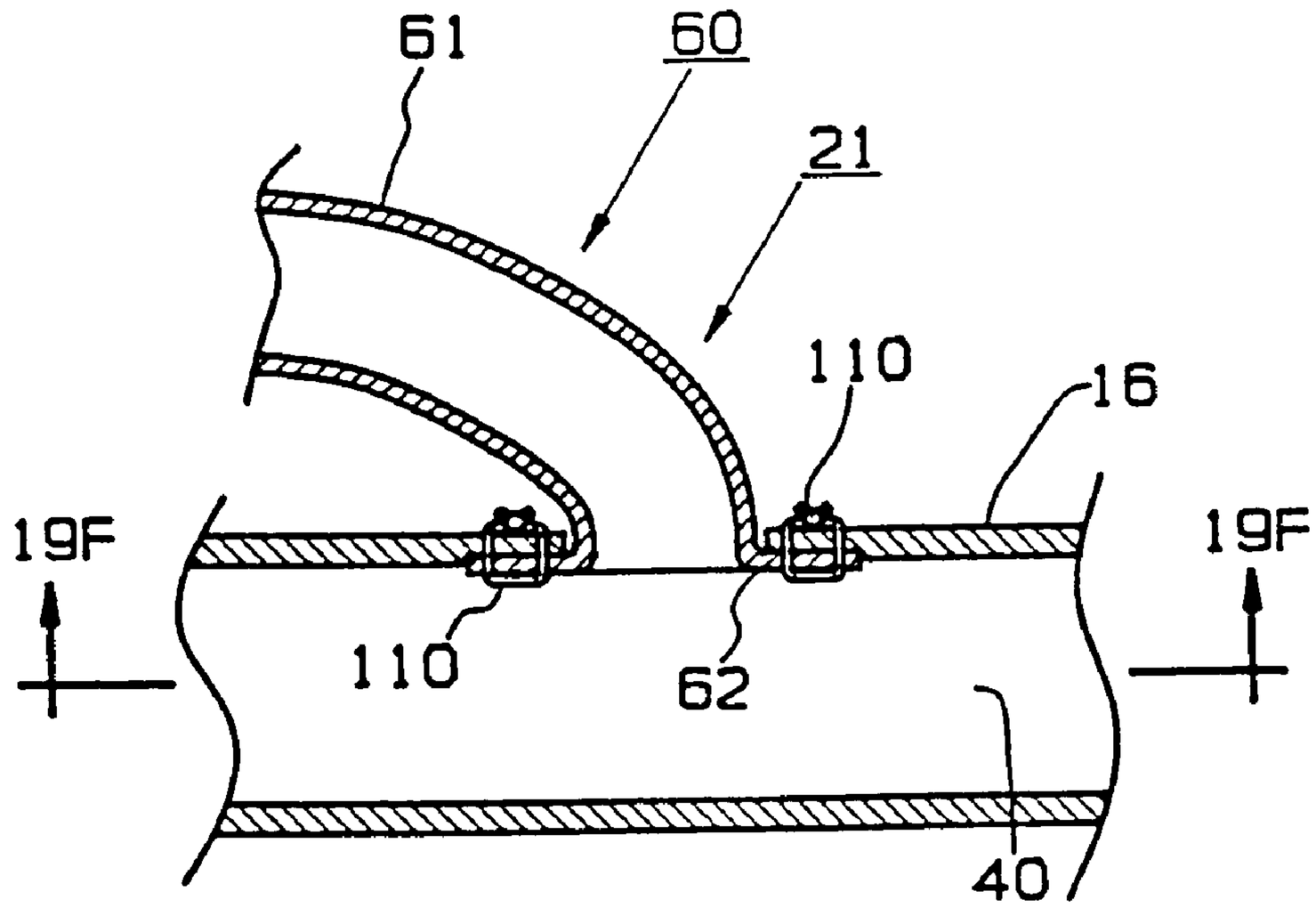
FIG. 19D



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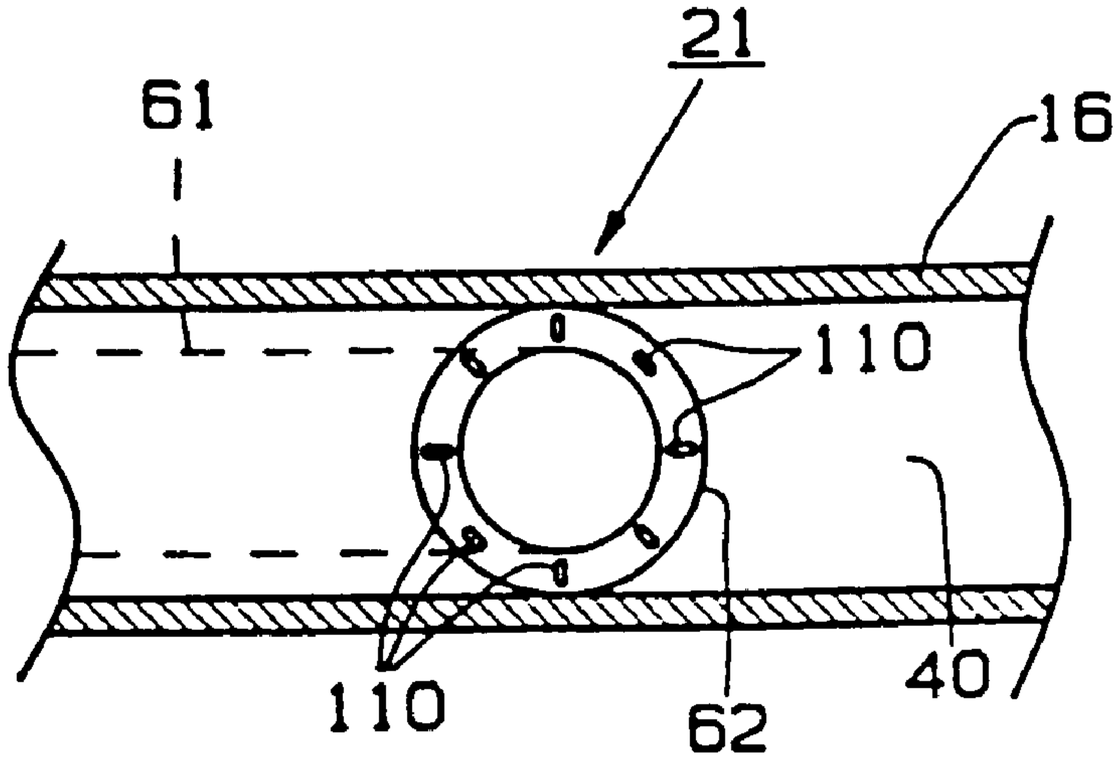

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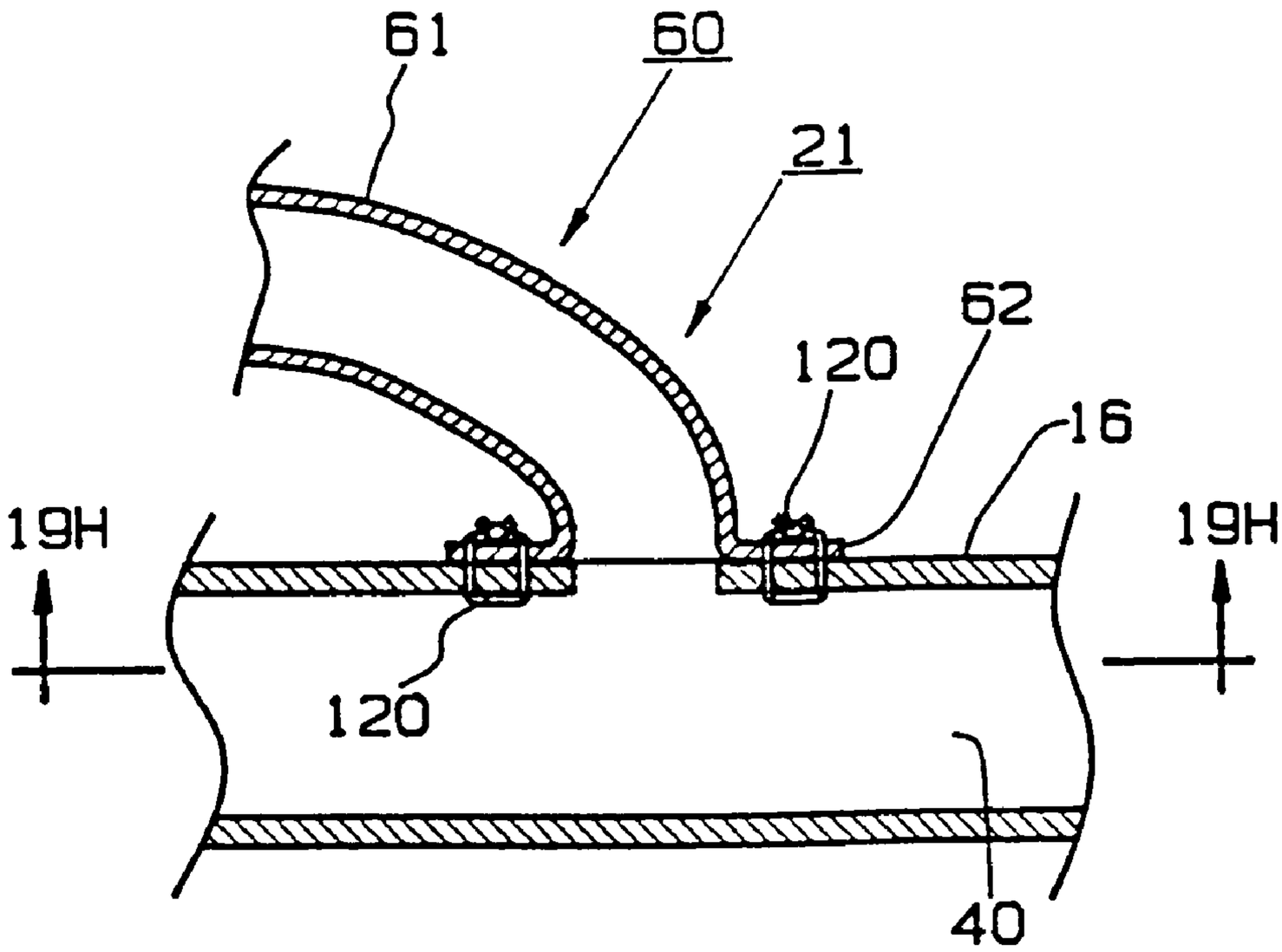


FIG. 19G

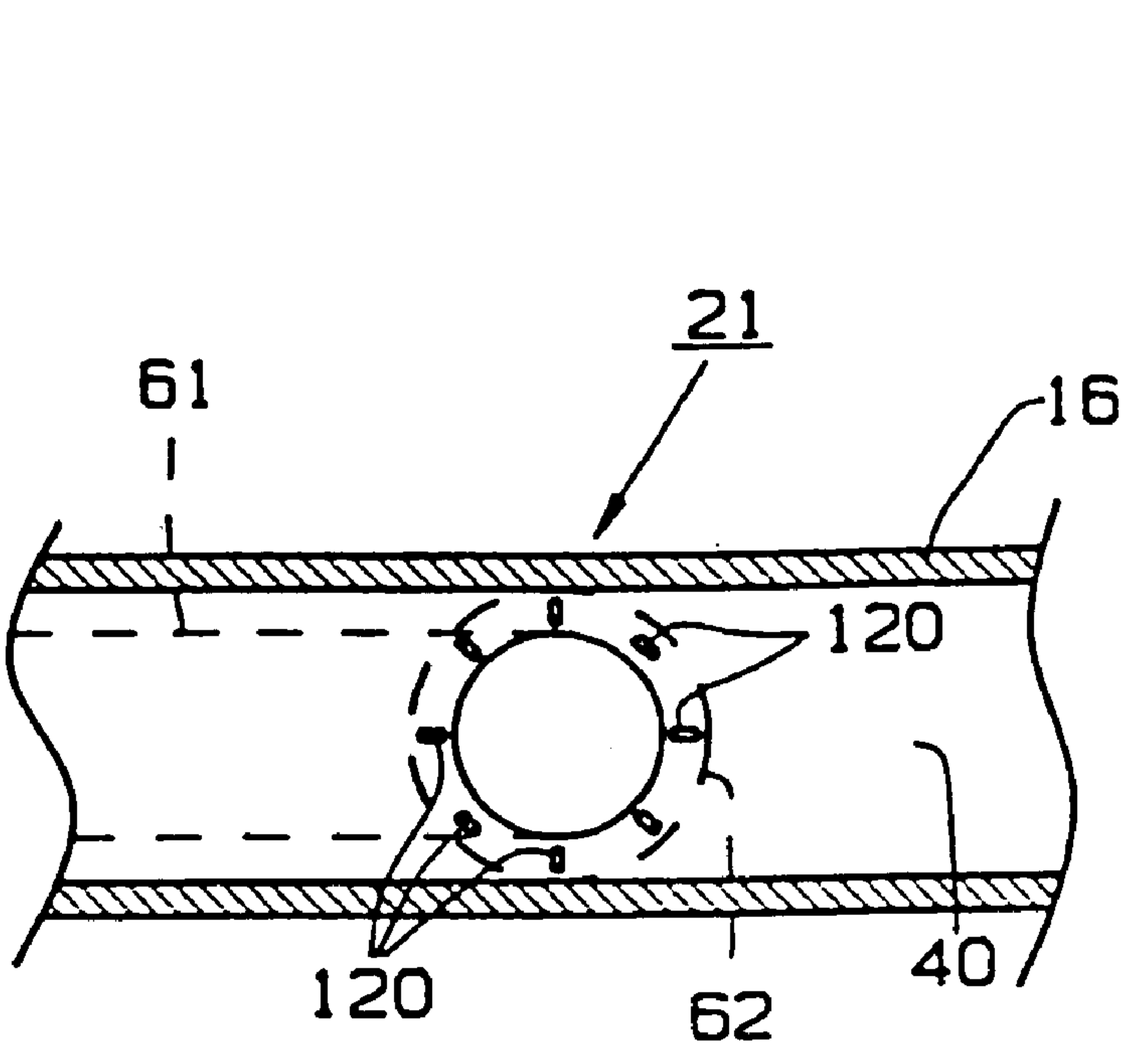
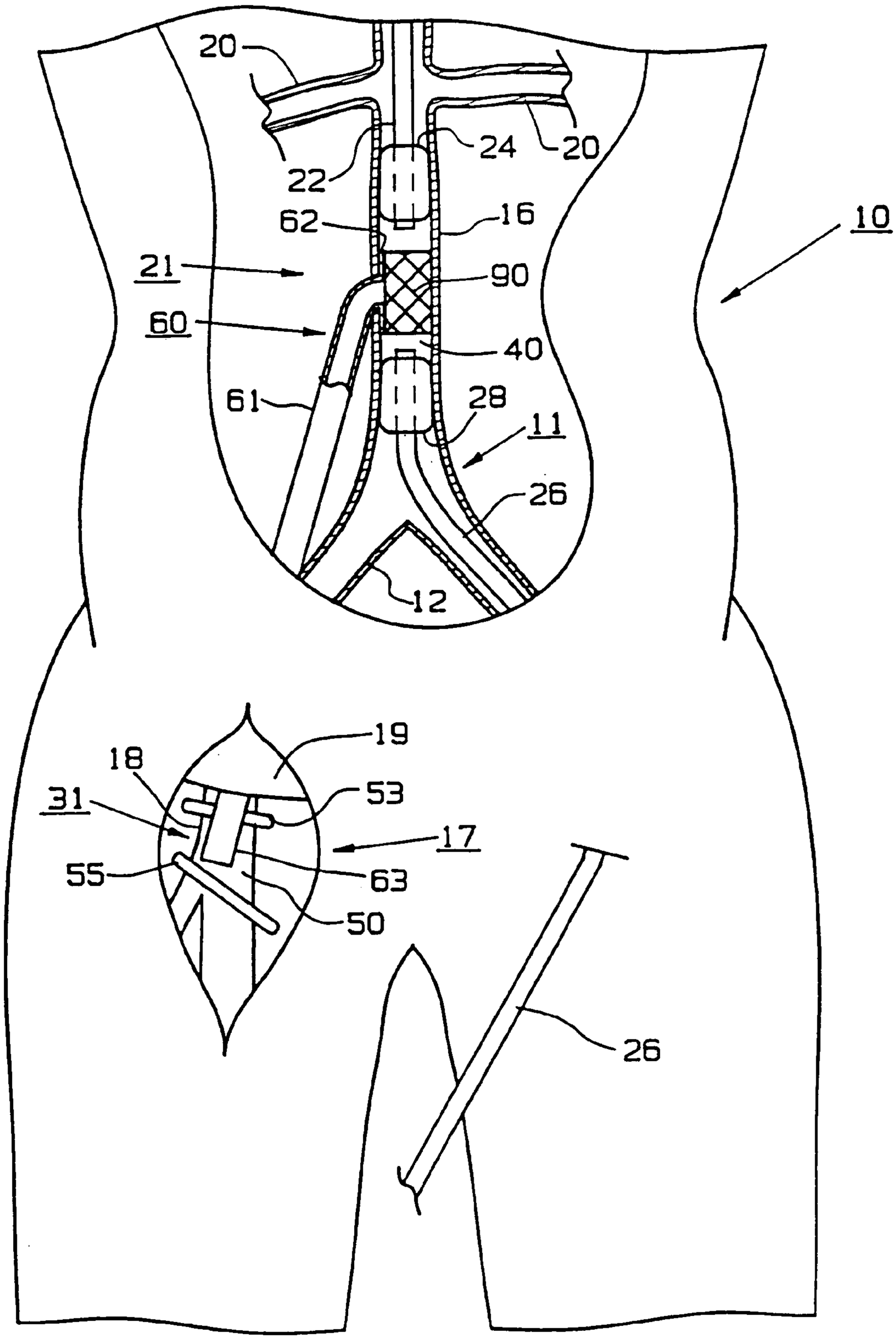


FIG. 19H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12
19
18
53
31
17
55
63
50
26

FIG. 21

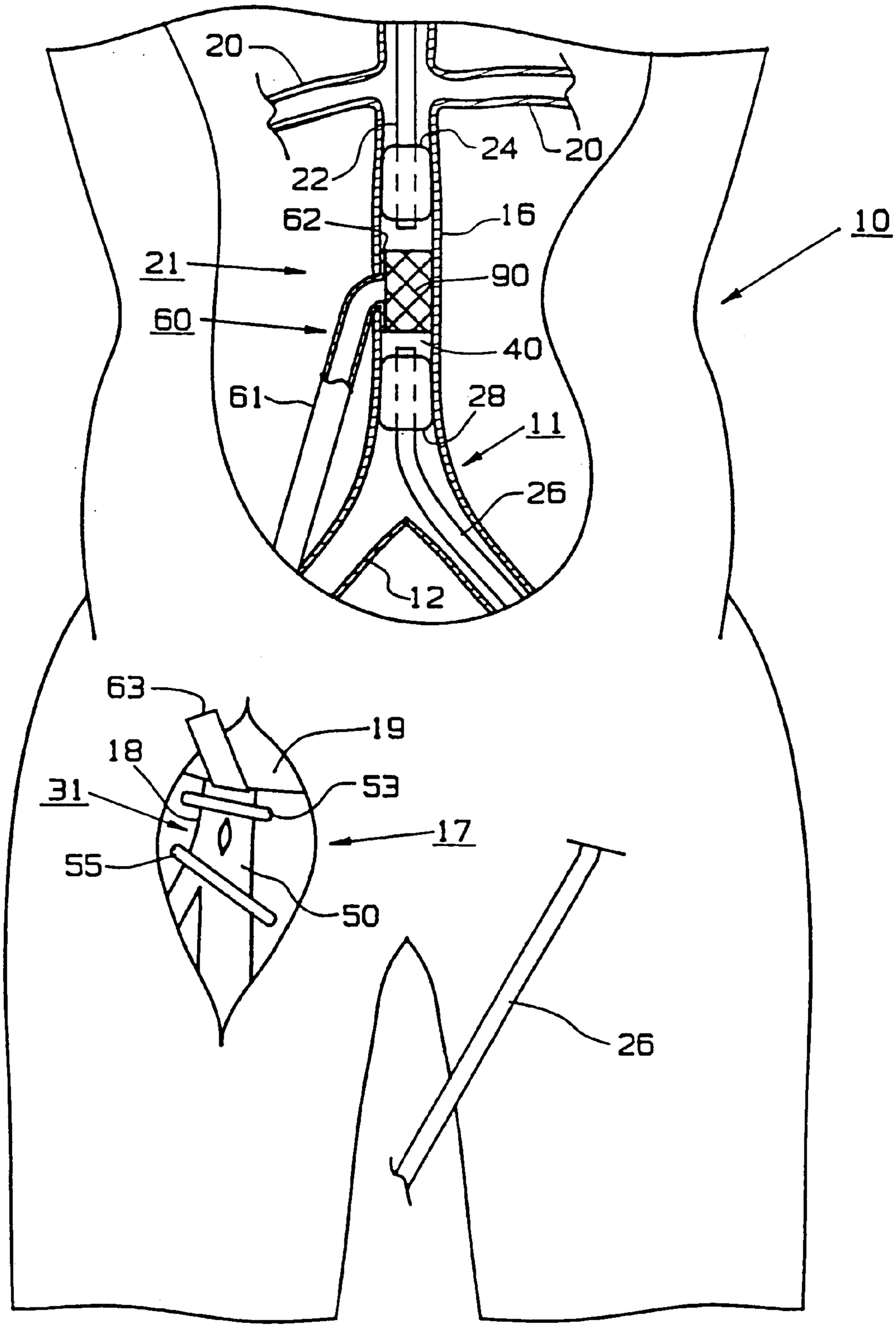
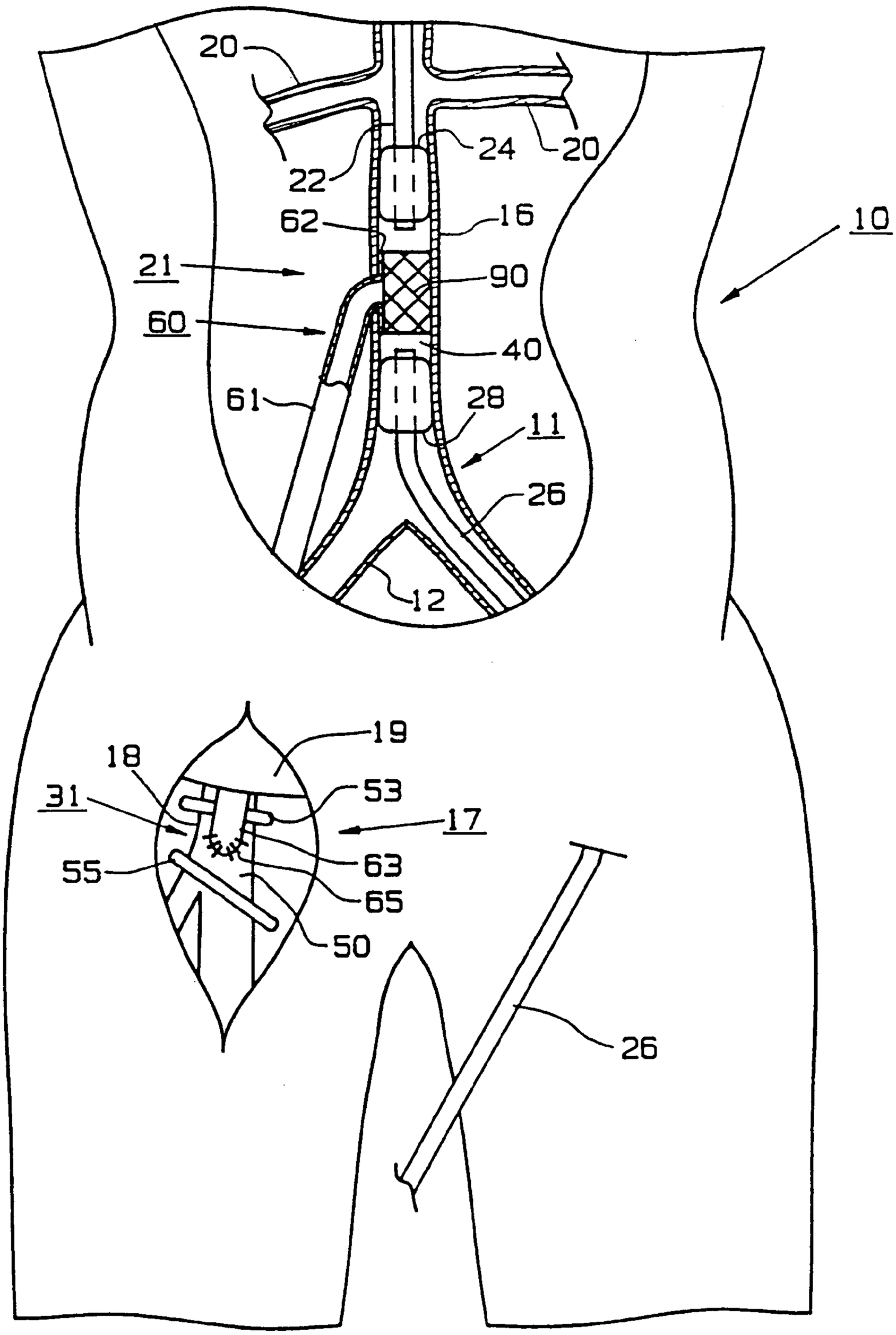

20
22
24
20
62
16
10
21
90
60
40
61
28
11
26
12
63
19
18
31
53
17
55
50
26

FIG. 22


20
22
24
20
62
16
10
21
90
60
40
61
28
11
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18
53
31
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65
50
26

Fig. 23

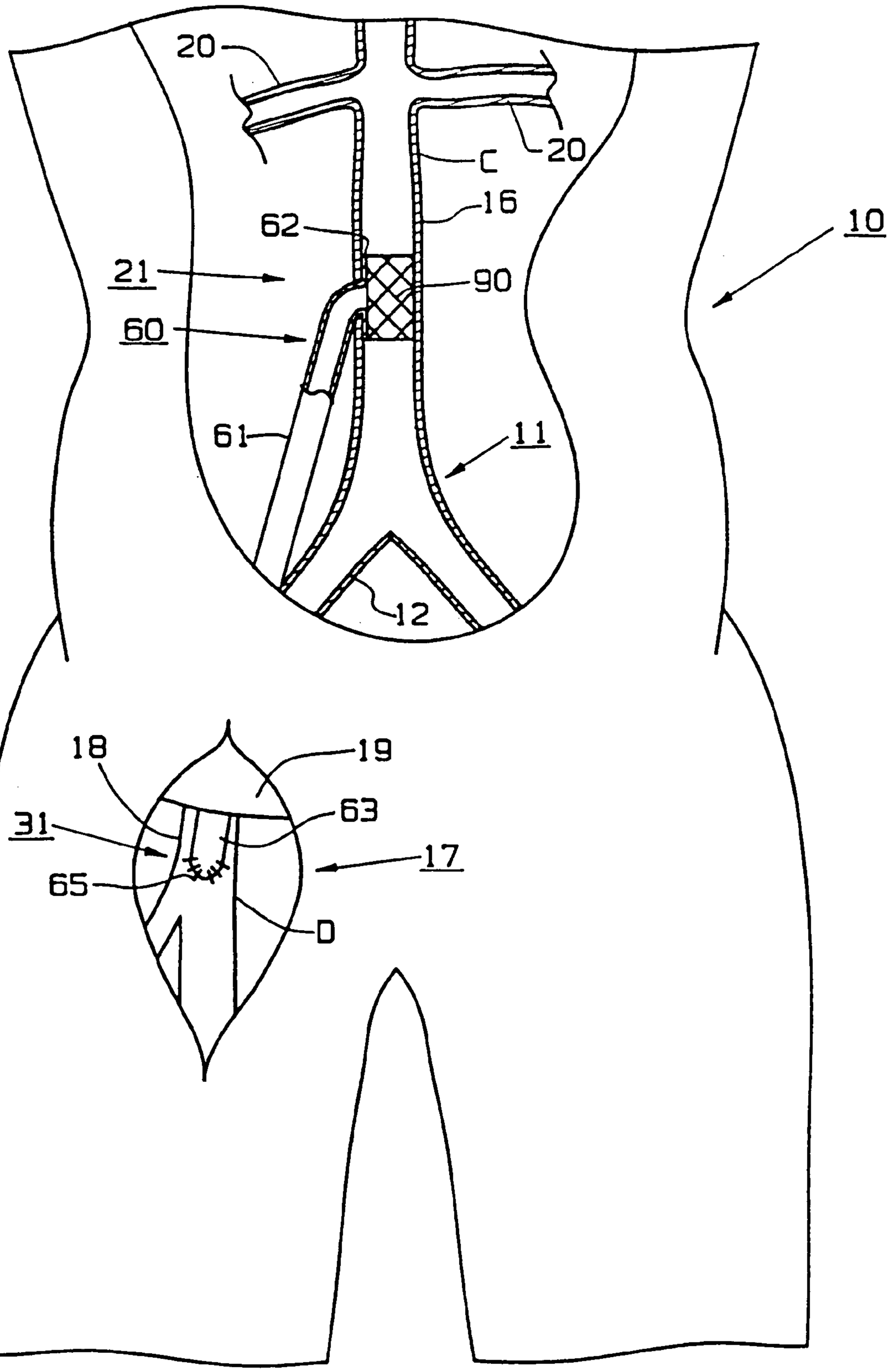

FIG. 24

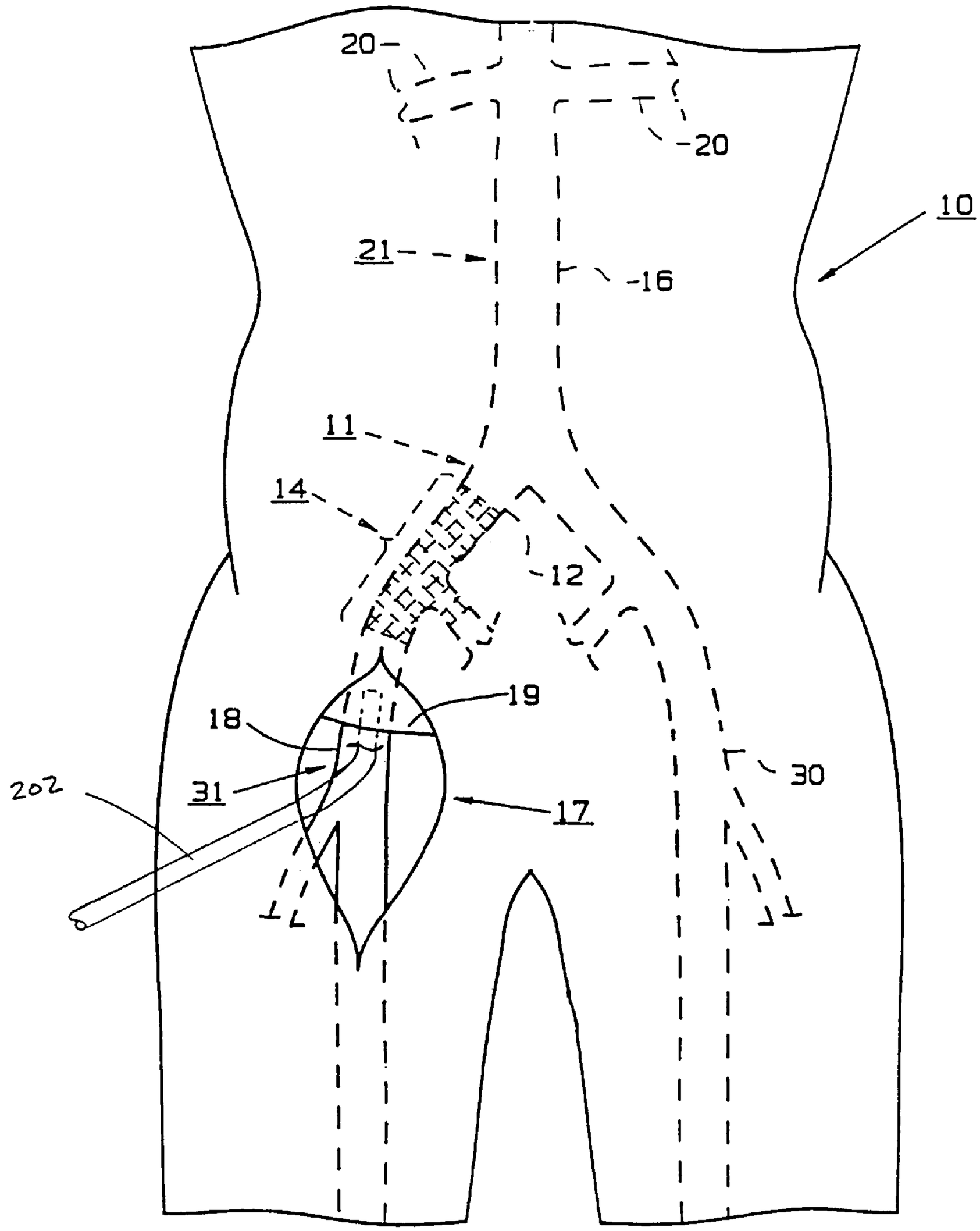

FIG. 25

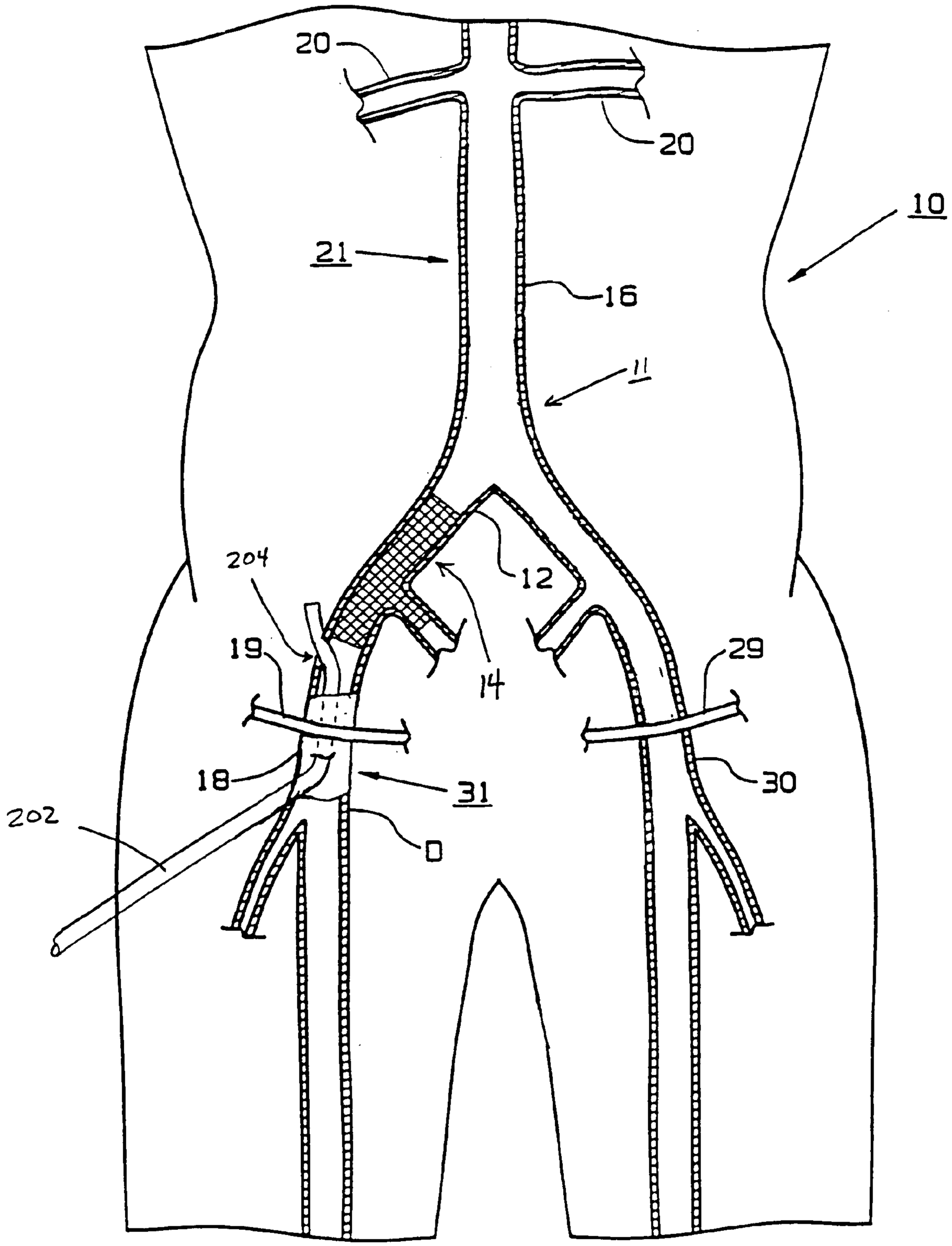

FIG. 26

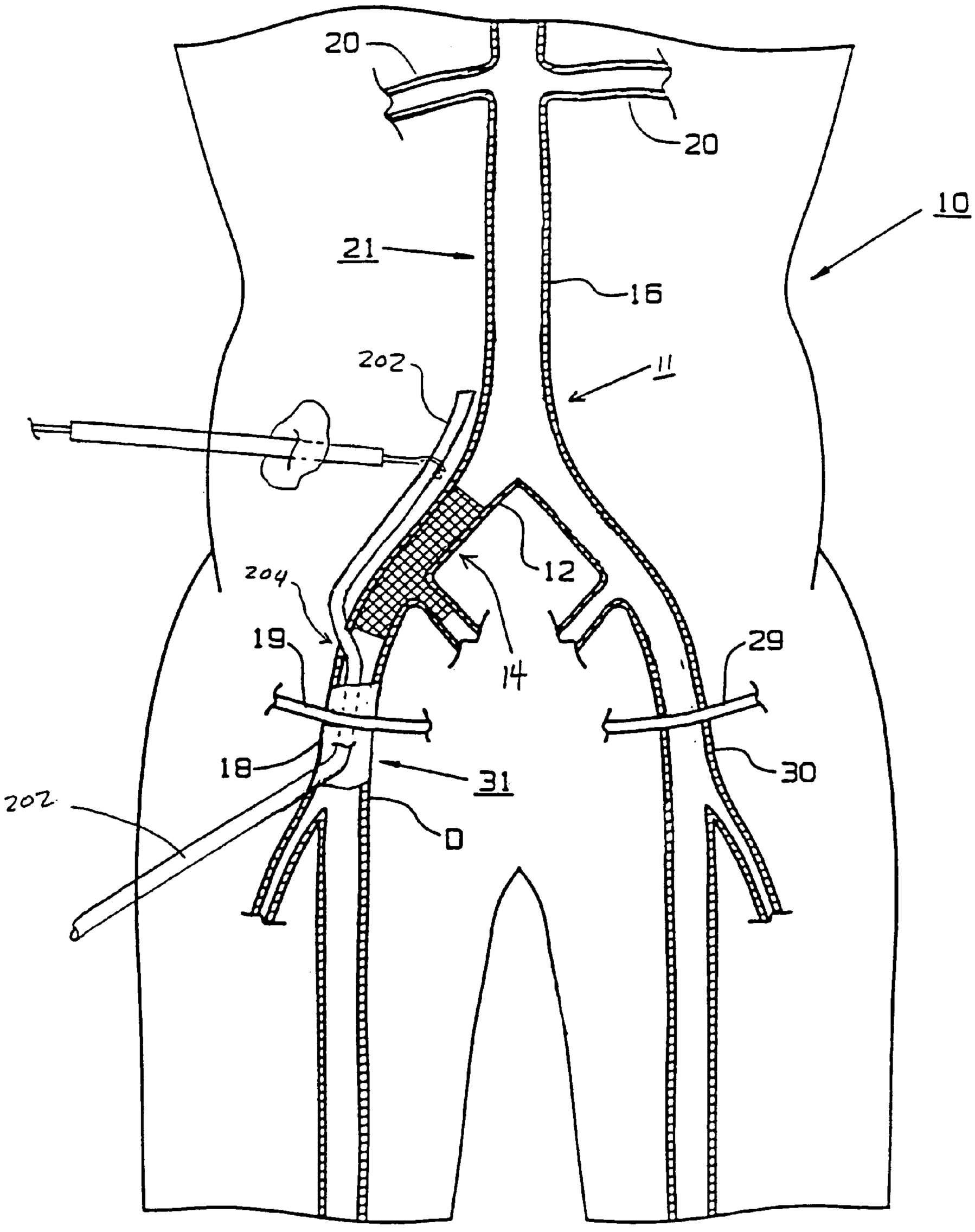

Fig. 27

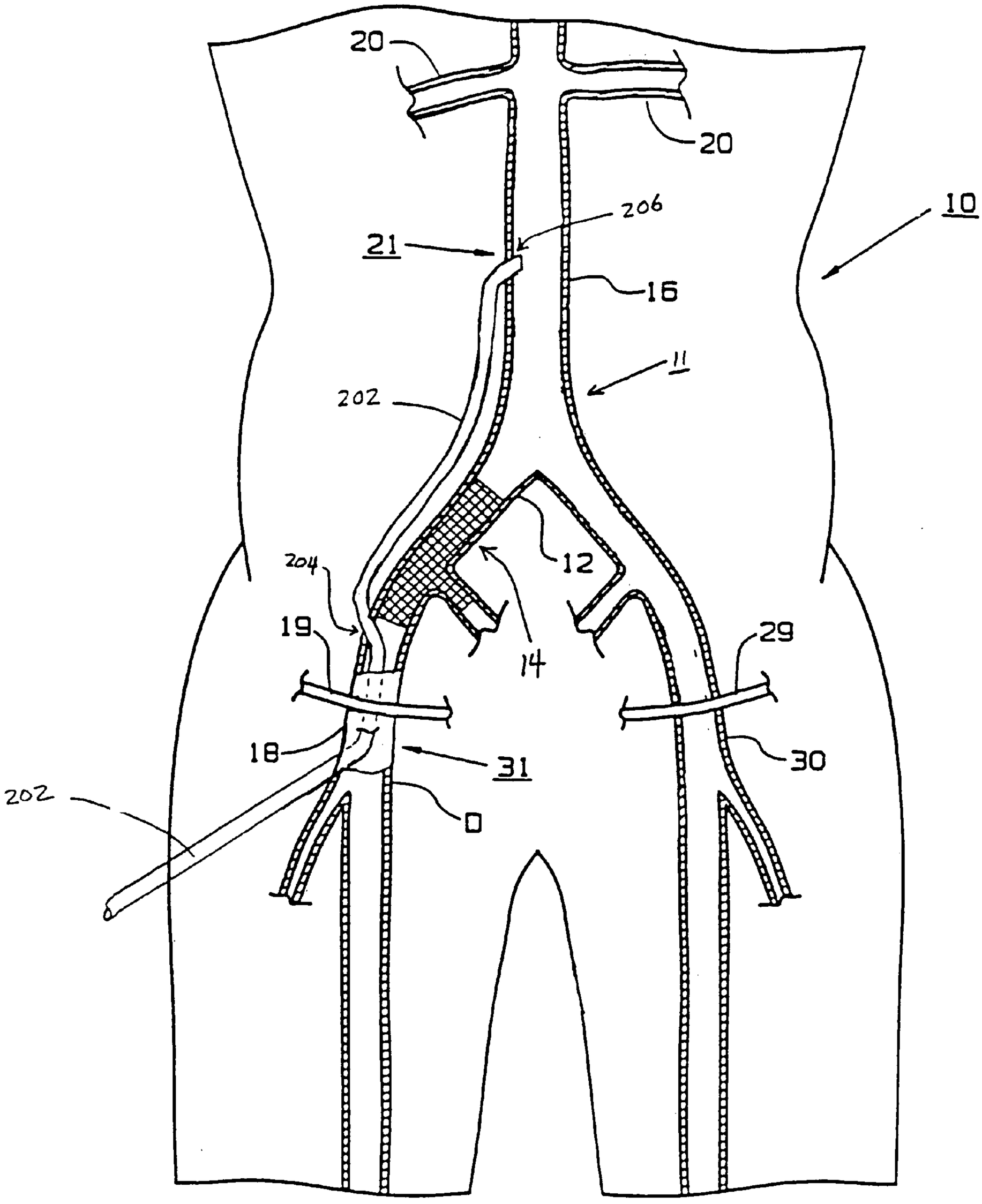

FIG. 28

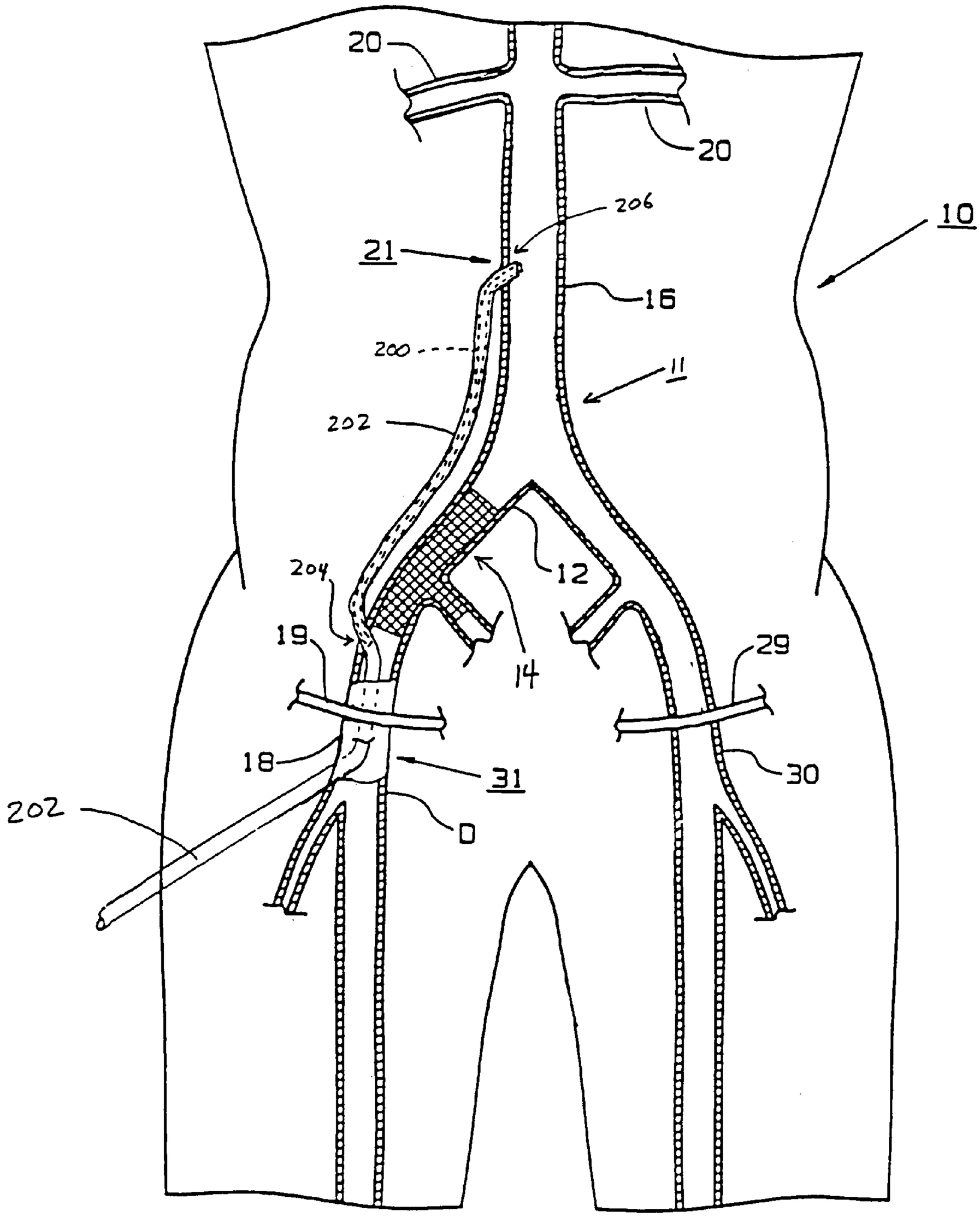

FIG. 29

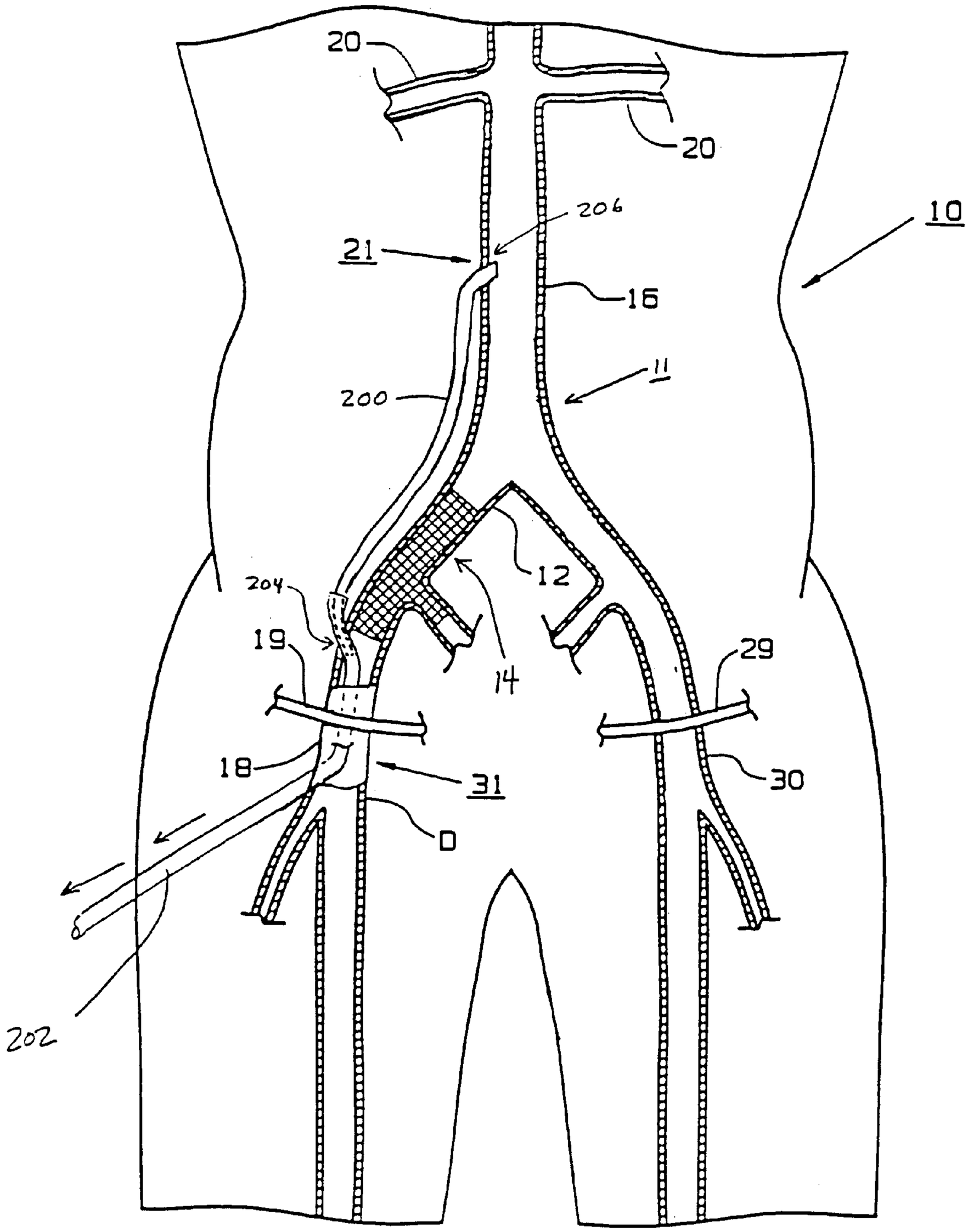

FIG. 30

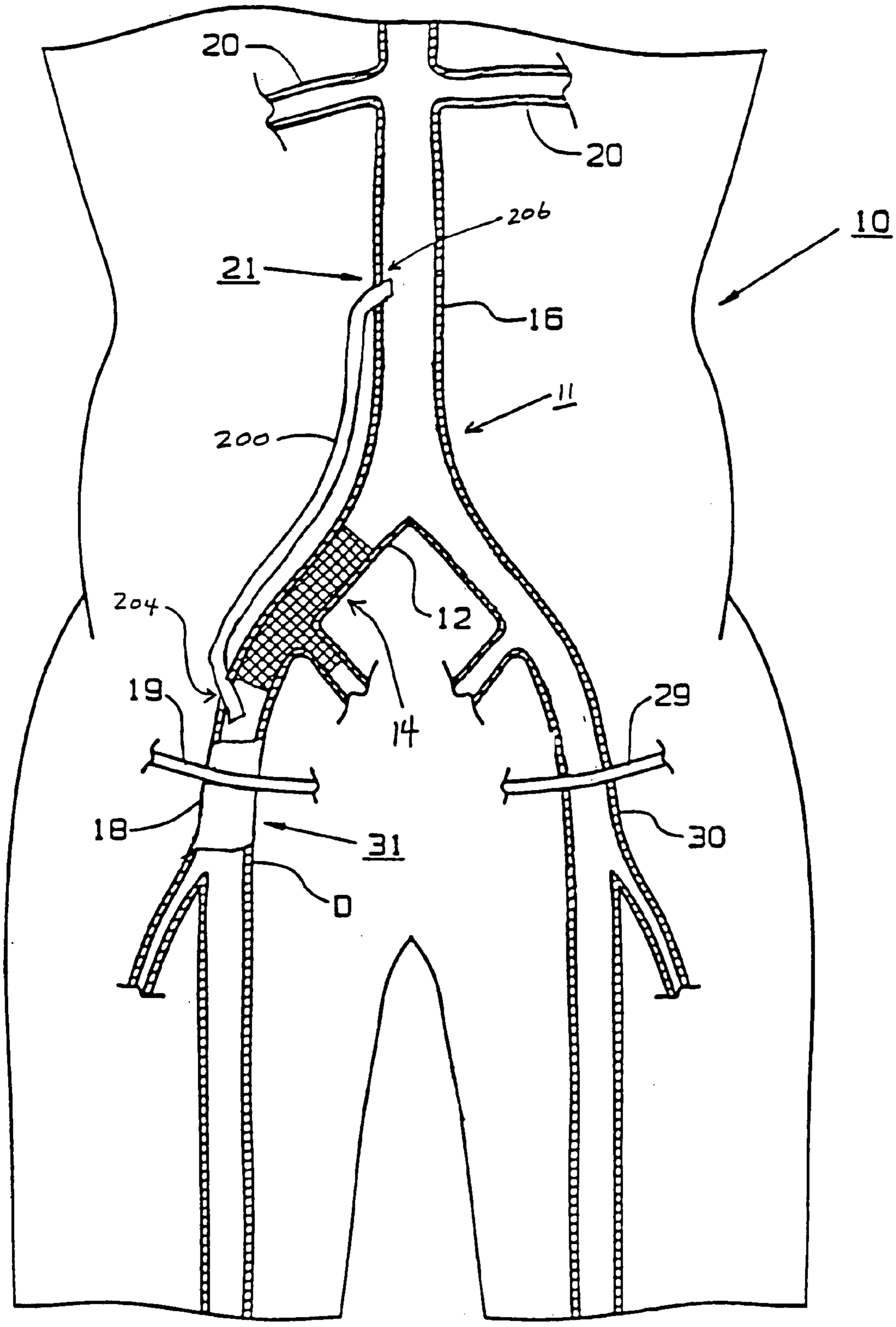

Fig. 31

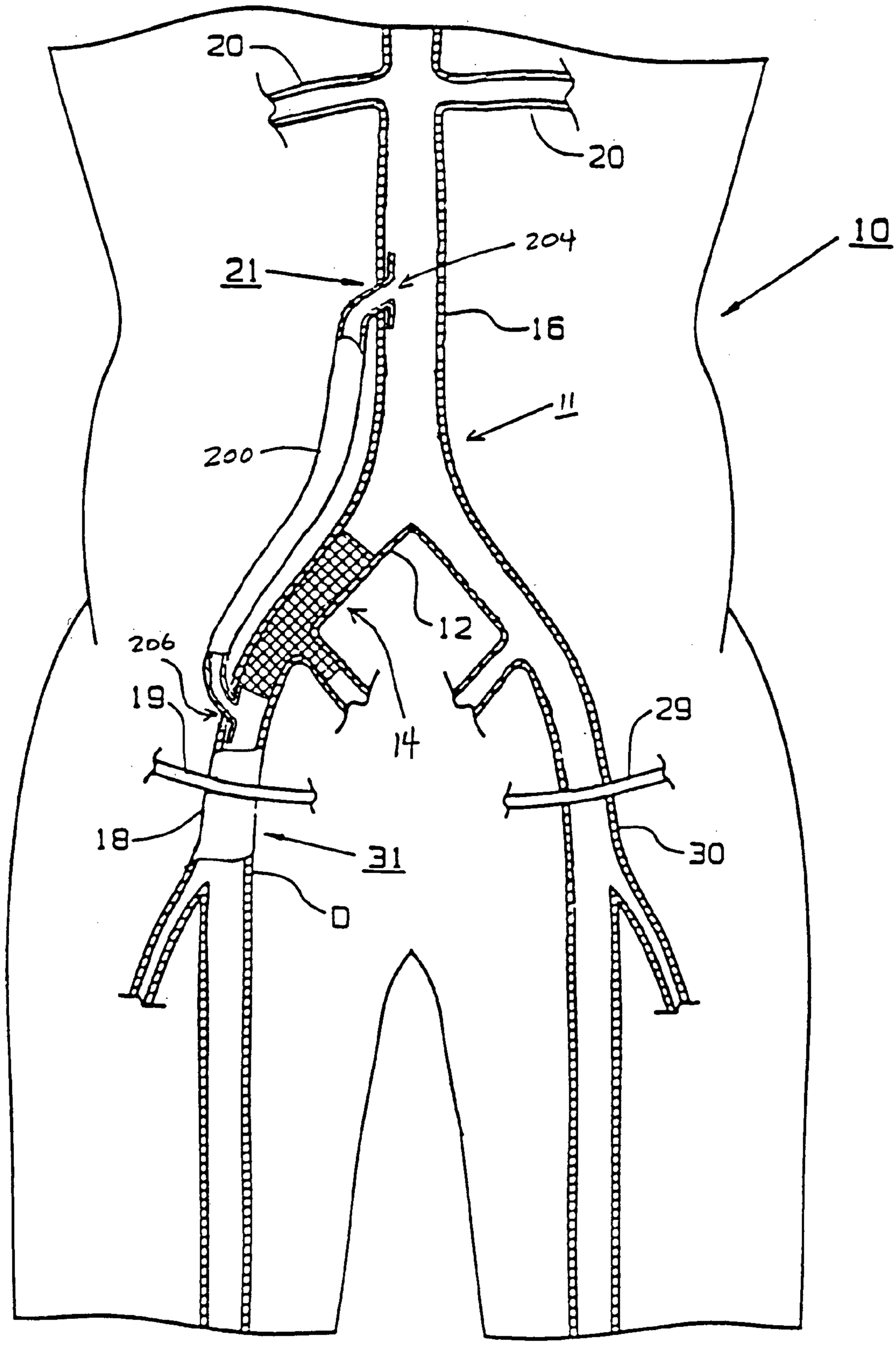

FIG. 32

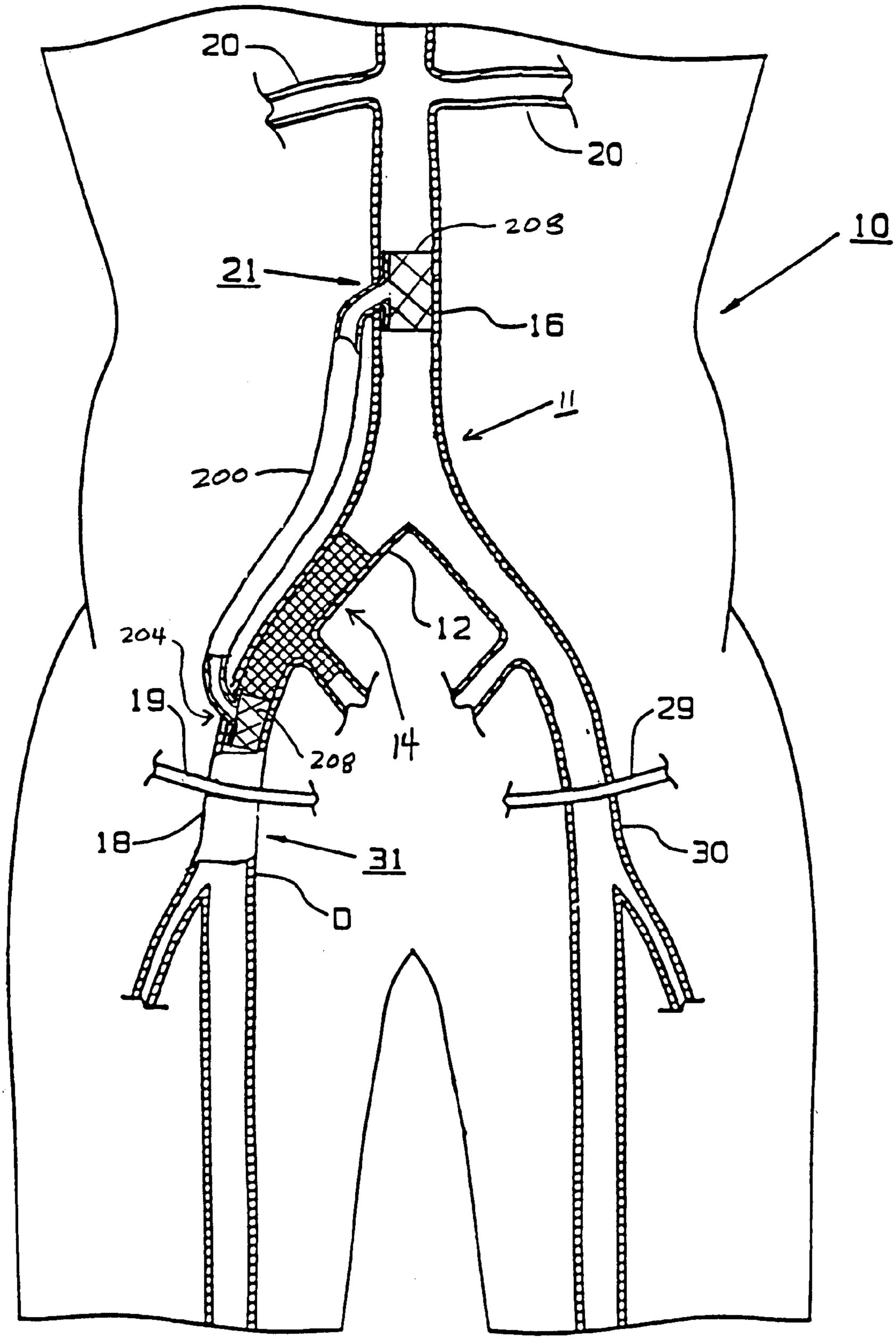

Fig. 33

BYPASS GRAFTING METHOD

RELATED CASES

This application is a continuation of application Ser. No. 09/903,831, filed on Jul. 11, 2001, entitled "Bypass Grafting Method", which is a continuation of Ser. No. 09/475,789, filed Dec. 30, 1999, now U.S. Pat. No. 6,599,313 which application is a continuation of application Ser. No. 09/111,062 filed Jul. 7, 1998, now abandoned, which in turn is a continuation of application Ser. No. 09/090,598 filed Jun. 4, 1998, now U.S. Pat. No. 5,934,286, which is a continuation of application Ser. No. 09/073,336, filed May 5, 1998, now U.S. Pat. No. 5,979,455, which is a continuation of application Ser. No. 08/702,742, filed Aug. 23, 1996, now U.S. Pat. No. 5,749,375, which is a continuation of application Ser. No. 08/391,960, filed Feb. 21, 1995, now U.S. Pat. No. 5,571,167, which is a continuation of application Ser. No. 08/138,912, filed Oct. 18, 1993, now U.S. Pat. No. 5,456,712, which is in turn a division of application Ser. No. 08/056,371, filed on May 3, 1993, now U.S. Pat. No. 5,304,220, which is a continuation-in-part of application Ser. No. 07/725,597, filed on Jul. 3, 1991, now U.S. Pat. No. 5,211,683.

BACKGROUND OF THE INVENTION

The present invention relates generally to a method for improving blood flow in the body of a patient and more particularly concerns an extravascular bypass grafting method which utilizes an intravascular approach.

Treatment of vascular disease in which the lumen of a blood vessel is significantly narrowed or occluded by atherosclerosis includes surgical and endovascular methods. Conventional surgical methods include obtaining access to a blood vessel via one or more surgical incisions and either removing the blockage by performing an endarterectomy or bypassing the blockage by placing a bypass graft which has a generally cylindrical shape. Endovascular methods include obtaining access to a blood vessel with a catheter and improving blood flow therein by performing an athrectomy, atherolysis, or balloon and laser angioplasty with or without endovascular stent placement. In general, the preferred treatment of severe stenosis or occlusion of a long vessel segment has been surgical bypass grafting.

Although conventional surgical bypass grafting is an accepted procedure, it presents substantial morbidity and mortality risks. Also, not all patients are acceptable candidates for the above surgical procedure due to advanced age and preexisting medical conditions. Moreover, conventional surgical bypass grafting is an invasive procedure which may require extended hospitalization due to postoperative recovery. In addition, the above surgical procedure may involve substantial financial costs to patients, hospitals and society in general. Further, incisions made during the above surgical procedure may cause significant cosmetically unattractive scarring which is undesirable to many patients.

SUMMARY OF THE INVENTION

One embodiment of the present invention involves a method of implanting a graft prosthesis in the body of a patient to bypass a segment of a blood vessel. The method includes the steps of (1) making an incision in the body, (2) positioning a graft so that one end of the graft is located substantially adjacent the blood vessel at a site upstream of the segment and a second end of the graft is located substantially adjacent the blood vessel at a site downstream of the segment, wherein the positioning step includes the step of placing the graft into the body through the incision, and further wherein the positioning step is performed while the upstream site is covered by a substantially intact portion of the epidermis of the body, (3) isolating a region of the area within the blood vessel substantially adjacent the upstream site from fluid communication with the rest of the area within the blood vessel, wherein the upstream isolating step is performed while the upstream site is covered by the substantially intact portion of the epidermis of the body, (4) making an arteriotomy in a sidewall of the blood vessel substantially adjacent the upstream site to create a communicating aperture between the upstream isolated region and an area outside of the blood vessel, wherein the upstream arteriotomy making step is performed while the upstream site is covered by the substantially intact portion of the epidermis of the body, (5) forming an anastomosis between the one end of the graft and the blood vessel substantially adjacent the upstream site, wherein the upstream anastomosis forming step is performed while the upstream site is covered by the substantially intact portion of the epidermis of the body, and further wherein the upstream anastomosis forming step includes the step of suturing the one end of the graft to the blood vessel, (6) isolating a region of the area within the blood vessel substantially adjacent the downstream site from fluid communication with the rest of the area in the blood vessel, (7) making an arteriotomy in the sidewall of the blood vessel substantially adjacent the downstream site to create a communicating aperture between the downstream isolated region and the area outside of the blood vessel, and (8) forming an anastomosis between the second end of the graft and the blood vessel substantially adjacent the downstream site.

Another embodiment of the present invention involves a method for implanting an end portion of a graft within the body of a patient during a bypass grafting procedure. The method includes the steps of (1) making an incision in the body at a first location, (2) isolating a region of the area within a blood vessel of the body substantially adjacent a second location from fluid communication with the rest of the area within the blood vessel, wherein the first location is remote from the second location, and further wherein the isolating step is performed while the second location is covered by a substantially intact portion of the epidermis of the body, (3) making an arteriotomy in the sidewall of the blood vessel substantially adjacent the second location to create a communicating aperture between the isolated region and the outside of the blood vessel, wherein the arteriotomy making step is performed while the second location is covered by the substantially intact portion of the epidermis of the body, (4) advancing the end portion of the graft through the incision to the second location, wherein the advancing step is performed while the second location is covered by the substantially intact portion of the epidermis of the body, and (5) forming an anastomosis between the end portion of the graft and the blood vessel substantially adjacent the second location, wherein the anastomosis forming step is performed while the second location is covered by the substantially intact portion of the epidermis of the body, and further wherein the anastomosis forming step includes the step of suturing the end portion of the graft to the blood vessel.

Still another embodiment of the present invention involves a graft which is securable to a sidewall of a blood vessel having an arteriotomy defined therein. The graft includes a body portion, and a flanged end portion attached

to the body portion, the flanged end portion being positionable substantially adjacent a portion of the sidewall of the blood vessel which substantially surrounds the arteriotomy.

Yet another embodiment of the present invention involves a graft and stent assembly which is securable to a sidewall of a blood vessel having an arteriotomy defined therein. The graft and stent assembly includes a graft having an end portion which is positionable within the blood vessel and substantially adjacent a portion of the sidewall of the blood vessel which substantially surrounds the arteriotomy. The graft and stent assembly further includes a stent positionable within the blood vessel and in contact with the end portion of the graft so as to secure the end portion of the graft between the sidewall of the blood vessel and the stent.

One object of the present invention is to provide an improved method for implanting a graft prosthesis in the body of a patient.

Another object of the present invention is to provide an improved method for implanting an end portion of a graft within the body of a patient.

Still another object of the present invention is to provide a method of implanting a graft prosthesis in the body of a patient which is less invasive relative to conventional surgical bypass grafting procedures.

Yet another object of the present invention is to provide a method of implanting a graft prosthesis in the body of a patient which obviates at least one surgical incision (e.g. the abdominal surgical incision) as compared to conventional surgical bypass grafting procedures.

Still another object of the present invention is to provide a method of implanting a graft prosthesis in the body of a patient which has low morbidity and mortality risk to patients.

Yet another object of the present invention is to provide a method of implanting a graft prosthesis in the body of a patient which can be performed on patients whom are elderly or have poor preexisting medical conditions.

Still another object of the present invention is to provide a method of implanting a graft prosthesis in the body of a patient which requires relatively less financial costs to patients, hospitals and society in general as compared to conventional surgical bypass grafting techniques.

Yet another object of the present invention is to provide an improved graft prosthesis.

Still another object of the present invention is to provide an improved graft and stent assembly.

Another object of the present invention is to provide a graft which can be conveniently secured to a blood vessel.

Yet another object of the present invention is to provide a graft and stent assembly which allows the graft to be conveniently secured to a blood vessel.

Yet still another object of the present invention is to provide a graft which is easy to implant in the body of a patient.

Still another object of the present invention is to provide a graft and stent assembly which is easy to implant in the body of a patient.

Another object of the present invention is to provide a graft which functions well after it is implanted in the body of a patient.

Yet another object of the present invention is to provide a graft and stent assembly which functions well after it is implanted in the body of a patient.

Other objects and benefits of the present invention can be discerned from the following description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a fragmentary front elevational view of a human body showing a blood vessel which includes the aorta, the right common iliac artery, the right common femoral artery and the left common femoral artery wherein a segment of the blood vessel is occluded. FIG. **1** also shows a portion of each inguinal ligament of the human body.

FIG. **2** is an enlarged fragmentary view of the human body and blood vessel of FIG. **1**.

FIG. **3** shows the human body and blood vessel of FIG. **2** with a balloon-tip catheter positioned within the blood vessel wherein the balloon is inflated in accordance with the preferred method of the present invention.

FIG. **4** is a view similar to FIG. **3** but showing a second balloon-tip catheter positioned within the blood vessel wherein the second balloon is inflated in accordance with the preferred method of the present invention.

FIG. **5** is a view similar to FIG. **4** but showing the blood vessel in phantom except for a portion thereof that is exposed through a gaping surgical incision. Also shown exposed through the surgical incision in FIG. **5** is a portion of the right inguinal ligament.

FIG. **6** is a view similar to FIG. **5** but showing another portion of the blood vessel, including the aorta, exposed for clarity of description. Moreover, in FIG. **6**, a laparoscope (depicted schematically) is shown inserted through the surgical incision in accordance with the preferred method of the present invention.

FIG. **7** is a view similar to FIG. **6** but showing a needle positioned within the laparoscope in accordance with the preferred method of the present invention.

FIG. **8** is a view similar to FIG. **7** but showing the needle removed from the laparoscope and replaced with a scissors device in accordance with the preferred method of the present invention.

FIG. **9**A is an elevational view of a graft prosthesis used in carrying out the preferred method of the present invention.

FIG. **9**B is a fragmentary sectional view taken along the line **9**B—**9**B of FIG. **9**A as viewed in the direction of the arrows.

FIG. **9**C is a fragmentary perspective view of the graft prosthesis of FIG. **9**A showing its outwardly extending flanged end portion.

FIG. **9**D is another fragmentary perspective view of the graft prosthesis of FIG. **9**A showing its outwardly extending flanged end portion.

FIG. **9**E is a view similar to FIG. **9**C but showing a plurality of springs, in phantom, integrally positioned within the outwardly extending flanged end portion in addition to a portion of the sidewalls of the graft prosthesis of FIG. **9**A.

FIG. **9**F is an elevational view of one of the plurality of springs of FIG. **9**E.

FIG. **9**G is an elevational view of another of the plurality of springs of FIG. **9**E.

FIG. **9**H is an elevational view of yet another of the plurality of springs of FIG. **9**E.

FIG. **9**I is an elevational view of still another of the plurality of springs of FIG. **9**E.

FIG. **10**A is an elevational view of the graft prosthesis of FIG. **9**A wherein the graft prosthesis is in a rolled configuration.

FIG. **10**B is a cross-sectional view taken along the line **10**B—**10**B of FIG. **10**A as viewed in the direction of the arrows.

FIG. **11**A is an elevational view of the laparoscope of FIG. **6**. Moreover, FIG. **11**A shows the graft prosthesis of FIG. **10**A, positioned within the laparoscope in accordance with the method of the present invention. FIG. **11**A further shows a plunger, used in carrying out the preferred method of the present invention, partially positioned within the laparoscope in accordance with the preferred method of the present invention.

FIG. **11**B is a cross-sectional view taken along the line **11**B—**11**B of FIG. **11**A as viewed in the direction of the arrows.

FIG. **12** is a view similar to FIG. **8** but showing the scissors device removed from the laparoscope and replaced with the graft prosthesis and plunger of FIG. **11**A in accordance with the preferred method of the present invention.

FIG. **13** is a view similar to FIG. **12** but showing the graft prosthesis being advanced out the distal end of the laparoscope in accordance with the preferred method of the present invention.

FIG. **14** is a view similar to FIG. **13** but showing the graft prosthesis being further advanced out the distal end of the laparoscope in accordance with the preferred method of the present invention.

FIG. **15** is a view similar to FIG. **14** but showing the graft prosthesis being yet further advanced out the distal end of the laparoscope in accordance with the preferred method of the present invention.

FIG. **16** is a view similar to FIG. **15** but showing the laparoscope removed from the surgical incision and showing the graft prosthesis after it had reverted back to its prerolled configuration in accordance with the preferred method of the present invention.

FIG. **17** is a view similar to FIG. **16** but showing a third balloon-tip catheter having a balloon thereon and further having an expandable stent, in its unexpanded state, positioned over the balloon, advanced to a position within the blood vessel in accordance with the preferred method of the present invention.

FIG. **18** is a view similar to FIG. **17** but showing the balloon of the third balloon-tip catheter inflated so as to expand the stent in to its expanded configuration in accordance with the preferred method of the present invention.

FIG. **19**A is a view similar to FIG. **18** but showing the third balloon-tip catheter removed from the blood vessel and showing the stent expanded to form an anastomosis between one end of the graft prosthesis and the blood vessel in accordance with the preferred method of the present invention.

FIG. **19**B is an enlarged schematic side elevational view showing a number of sutures tied to the sidewall of the blood vessel so as to secure the end portion of the graft and the stent thereto as a possible additional procedure in order to further ensure the integrity of the anastomosis of FIG. **19**A.

FIG. **19**C is a cross-sectional view taken along the line **19**C—**19**C of FIG. **19**B as viewed in the direction of the arrows.

FIG. **19**D is a view similar to FIG. **19**A but showing a laparoscope (depicted schematically) inserted through an incision in the epidermis of the body and into the peritoneal cavity, and further showing a grasper holding a curved needle with an end of a suture attached thereto wherein the distal end of the grasper is positioned at the upstream site.

FIG. **19**E is an enlarged schematic side elevational view showing a number of sutures tied to the sidewall of the blood vessel so as to secure the end portion of the graft thereto (without the use of the stent), wherein the end portion of the graft is positioned within the upstream isolated region, as an alternative procedure in forming an anastomosis between the end portion of the graft and the blood vessel.

FIG. **19**F is a cross-sectional view taken along the line **19**F—**19**F of FIG. **19**E as viewed in the direction of the arrows.

FIG. **19**G is an enlarged schematic side elevational view showing a number of sutures tied to the sidewall of the blood vessel so as to secure the end portion of the graft thereto (without the use of the stent), wherein the end portion of the graft is positioned outside of the upstream isolated region, as another alternative procedure in forming an anastomosis between the end portion of the graft and the blood vessel.

FIG. **19**H is a cross-sectional view taken along the line **19**H—**19**H of FIG. **19**G as viewed in the direction of the arrows.

FIG. **20**A is an enlarged side elevational view showing the anastomosis of FIG. **19**A.

FIG. **20**B is a cross-sectional view taken along the line **20**B—**20**B of FIG. **20**A as viewed in the direction of the arrows.

FIG. **20**C is a cross-sectional view taken along the line **20**C—**20**C of FIG. **20**A as viewed in the direction of the arrows.

FIG. **21** is a view similar to FIG. **19**A but showing a pair of clamps positioned on the blood vessel in accordance with the preferred method of the present invention.

FIG. **22** is a view similar to FIG. **21** but showing an arteriotomy formed in the sidewall of the blood vessel in accordance with the preferred method of the present invention.

FIG. **23** is a view similar to FIG. **22** but showing an anastomosis formed between the other end the graft prosthesis and the blood vessel in accordance with the preferred method of the present invention.

FIG. **24** is a view similar to FIG. **23** but showing the first balloon-tip catheter and the second balloon-tip catheter removed from the blood vessel in accordance with the preferred method of the present invention.

FIGS. **25**–**33** are views showing performance of a bypass grafting procedure in accordance with the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments and methods illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated devices and methods, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring now to the drawings, FIG. **1** shows a portion of a human body, generally designated by the reference numeral **10**, with an artery, the common iliac artery **12**, having an occluded segment, generally designated by the reference numeral **14**. Human body **10** is further shown having other arteries, in particular, aorta **16**, right common femoral artery **18**, left common femoral artery **30** and renal arteries **20**. In addition, human body **10** includes a right inguinal ligament **19** and a left inguinal ligament **29**. Human body **10** also includes an epidermis **13** (see e.g. FIG. **6**). The preferred method disclosed herein describes the implantation of a graft to couple aorta **16** to right common femoral

artery **18** thereby bypassing occluded segment **14**. FIG. **2** shows an enlarged view of aorta **16**, right common iliac artery **12**, occluded segment **14**, right common femoral artery **18**, left common femoral artery **30**, renal arteries **20** and right inguinal ligament **19**. In FIGS. **1** and **2**, a blood vessel is shown, generally designated by the reference numeral **11**, which includes aorta **16**, right common iliac artery **12**, right common femoral artery **18** and left common femoral artery **30**. Blood vessel **11**, when not occluded, conveys blood from a point C within aorta **16** to a point D within right common femoral artery **18** (see FIGS. **1**–**2**). However, due to the presence of occluded segment **14**, blood is substantially totally precluded from being conveyed from point C within aorta **16** to point D within right common femoral artery **18** via the direct route of right common iliac artery **12**. While the inventive method will hereinafter be described with regard to a substantially totally occluded segment of a blood vessel of a patient, it will be understood to one skilled in the art that the inventive method is equally effective for bypass of a partially occluded segment of a blood vessel. In addition, the inventive method is also useful for bypass of an aneurysmal segment of a blood vessel.

Referring now to FIGS. **3**–**24**, successive steps according to the preferred method of the present invention are depicted of the implantation of a graft prosthesis of the present invention to couple aorta **16** to right common femoral artery **18** thereby bypassing occluded segment **14** of blood vessel **11**.

One step of the preferred method of the present invention comprises isolating a region of the area within the blood vessel **11**, located near a site **21** (see FIG. **4**) upstream of occluded segment **14**, from fluid communication with the rest of the area within the blood vessel. There also exists a site **31** which is located downstream of occluded segment **14** (see FIG. **4**). Upstream site **21** is located substantially adjacent the blood vessel **11** and designates a working area where the distal end of medical instruments and various medical devices may be positioned during the process of securing one end of a graft to the blood vessel. Upstream site **21** is located near blood vessel **11** so as to allow such distal end of medical instruments and medical devices to be appropriately manipulated at upstream site **21** to thereby successfully secure the one end of the graft to the blood vessel. Downstream site **31** is located substantially adjacent the blood vessel **11** and also designates a working area where the distal end of medical instruments, physician's hands and various medical devices may be positioned during the process of securing a second end of the graft to the blood vessel. Downstream site **31** is also located near blood vessel **11** so as to allow such distal end of medical instruments, physician's hands and medical devices to be appropriately manipulated at downstream site **31** to thereby successfully secure the second end of the graft to the blood vessel.

Referring now to FIG. **3**, a balloon-tip catheter **22** having a balloon **24** thereon is percutaneously inserted into blood vessel **11** via the right or left axillary artery (not shown). This step may be accomplished using standard catherization techniques. The distal end of catheter **22** is then advanced into aorta **16** until balloon **24** is positioned distal to renal arteries **20** as shown in FIG. **3**. Balloon **24** is then inflated to and maintained at a size such that fluid communication is substantially terminated in aorta **16** between the portion of blood vessel **11** proximal to balloon **24** and the portion of blood vessel **11** distal to balloon **24**. Since conventional balloon-tip catheters may not have a balloon thereon that possess the characteristics necessary to terminate fluid communication in the aorta as described above, modification may be readily made to an existing design of a conventional balloon-tip catheter to achieve the above desired results. One such modification would include providing a balloon on the catheter with is inflatable to an outer diameter which is larger than the inner diameter of the aorta. Another such modification would include providing a coarse textured outer surface to the balloon of the catheter. The above modification would provide increased frictional resistance between the inflated balloon and the sidewall of the blood vessel when force is applied to the balloon in the axial direction thereof. A balloon-tip catheter having a conventional design is available through Medi-tech, Incorporated of Watertown, Mass., as Order No. 17-207 (Description: OBW/40/8/2/100).

Referring now to FIG. **4**, a balloon-tip catheter **26** having a balloon **28** thereon and an open lumen defined therein is percutaneously inserted into blood vessel **11** via the left common femoral artery **30**. This step may be accomplished using standard catherization techniques. The distal end of the catheter **26** is then advanced into aorta **16** until balloon **28** is positioned proximal to the aortic bifurcation. Balloon **28** is then inflated to and maintained at a size such that fluid communication is substantially terminated in aorta **16** between the portion of blood vessel **11** proximal to balloon **28** and the portion of blood vessel **11** distal to balloon **28**. Since conventional balloon-tip catheters may not have a balloon thereon that possess the characteristics necessary to terminate fluid communication in the aorta as described above, modification similar to that described with respect to catheter **22** may need to be made to catheter **26**. In addition, further modification may need to be made to catheter **26** since a conventional balloon-tip catheter may not have an open central lumen defined therein which possesses a diameter large enough for the advancement therethrough of a compressed stent mounted on a balloon of another balloon-tip catheter as will be required by the preferred method of the present invention (see FIG. **17**). Such further modification would be to create an open central lumen in catheter **26** that possesses a diameter larger than the outer diameter of the compressed stent which is mounted on the balloon of the balloon-tip catheter as referred to above. Due to the increased size requirements of catheter **26** as alluded to above, a surgical cut-down may need to be performed in order to expose left common femoral artery **30**. Such exposure would facilitate both placement of catheter **26** into blood vessel **11** and repair of such blood vessel following subsequent removal of such catheter therefrom.

Temporary occlusion of the blood flow in the inferior mesenteric artery (not shown) by laparoscopic procedures may need to be performed in order to prevent the flow of blood from the inferior mesenteric artery into aorta **16** due to placement of inflated balloons **24** and **28** as discussed above.

The region bound by balloon **24** of catheter **22** and balloon **28** of catheter **26** and the sidewall of blood vessel **11** contained therebetween defines a region **40** of the area within blood vessel **11**, located near site **21** upstream of occluded segment **14**, which is substantially isolated from fluid communication with the rest of the area within blood vessel **11**.

Alternatively, the step of isolating the region of the area within blood vessel **11**, located near upstream site **21**, from fluid communication with the rest of the area within the blood vessel may be accomplished by laparoscopically placing a first clamp around the blood vessel **11** at the location where balloon **24** of the balloon-tip catheter **22** was described as having been inflated and also laparoscopically

placing a second clamp around the blood vessel **11** at the location where balloon **28** of the balloon-tip catheter **26** was described as having been inflated.

Another step according to the method of the present invention comprises making an arteriotomy in the sidewall of blood vessel **11**, near upstream site **21**, to create a communicating aperture between upstream isolated region **40** and the outside of blood vessel **11**.

Referring now to FIG. **5**, right common femoral artery **18** and right inguinal ligament **19** are exposed via a surgical incision **17**. Such exposure is accomplished using standard surgical techniques.

Insufflation of the peritoneal cavity is then performed using standard techniques associated with laparoscopy. A laparoscope **37** (see FIG. **6**), having an open central lumen (i.e. a working channel) defined therein, is then inserted into human body **10** through the opening between right common femoral artery **18** and right inguinal ligament **19**. Laparoscope **37** may additionally include a fiber optic illumination device and a telescope for viewing. A tilt table may be used with the patient (i.e. human body **10**) positioned thereon in order to maneuver the patient's abdominal contents away from the laparoscope insertion site and the area near upstream site **21**. Laparoscope **37** is then advanced toward upstream site **21** until its distal end is positioned thereat as shown in FIG. **6**. One or more additional laparoscopes and associated laparoscopic operating instruments may be employed using standard laparoscopic techniques to assist in the above positioning via direct visualization, tissue retraction and tissue dissection. One laparoscope which may be used in carrying out the preferred method of the present invention is available through Karl Storz Endoscopy-America. Incorporated of Culver City, Calif., as Catalog No. 26075A. Modification may be readily made to laparoscope **37**, such as rounding the distal edge thereof, in order to reduce the possibility of tissue trama as a result of advancement of laparoscope **37** within human body **10**. A book which discloses various standard laparoscopic techniques and standard associated laparoscopic operating instruments is entitled "Laparoscopy for Surgeons," authored by Barry A. Salky, M.D., published by Igaku-Shoin Medical Publishers, Inc. of New York, N.Y., U.S.A. (1990), and the pertinent part of the disclosure of which is herein incorporated by reference.

Referring now to FIG. **7**, a puncture needle **39** is advanced through the open central lumen of laparoscope **37** until its distal end exits the laparoscope. Thereafter, needle **39** is manipulated to penetrate through the sidewall of blood vessel **11** to the inside thereof, thus creating a puncture in the blood vessel. Needle **39** is then withdrawn and a scissors device **41** is advanced through the open central lumen of laparoscope **37** until its distal end exits the laparoscope (see FIG. **8**). The scissors device is then manipulated to enlarge the puncture in the sidewall of the blood vessel. Scissors device **41** is then withdrawn from laparoscope **37**. One puncture needle which may be used in carrying out the preferred method of the present invention is available through Karl Storz Endoscopy-America. Incorporated of Culver City, Calif. as Catalog No. 26178R. Additionally, one scissors device which may be used in carrying out the method of the present invention is available through Karl Storz Endoscopy-America. Incorporated of Culver City, Calif., as Catalog No. 26178PS.

It should be noted that if upstream isolated region **40** was not substantially isolated from fluid communication with the rest of the area within the blood vessel, the act of making an arteriotomy in the sidewall of blood vessel **11** near upstream site **21** would cause significant blood leakage out of blood vessel **11** and such blood leakage may be fatal to the patient.

According to another step of the method of the present invention, a graft prosthesis is positioned so that one end of the graft is located substantially adjacent blood vessel **11** at downstream site **21** and the other end of the graft prosthesis is located substantially adjacent blood vessel **11** at downstream site **31**. The above positioning step includes the step of advancing the graft prosthesis within the human body **10** with a medical instrument.

One type of graft prosthesis which may be used is a graft, generally designated by the reference numeral **60** and shown in FIGS. **9**A–**9**E. Graft **60** includes a body portion **61** having a length slightly larger than the distance between upstream site **21** and downstream site **31**. Graft **60** has an outwardly extending flanged end portion **62** as shown in FIGS. **9**A, **9**C, **9**D and **9**E. End portion **62** is resiliently maintained outwardly extending by four springs **64**A–**64**D as shown in FIGS. **9**B and **9**E–**9**I. In their relaxed state, springs **64**A–**64**D maintain end portion **62** within a plane P**1** as shown in FIG. **9**A. It should be noted that a number of springs other than four may be used, if desired, to maintain end portion **62** outwardly extending as previously shown and described. Graft **60** further includes a second end portion **63** having a design similar to that of a conventional prosthetic graft as shown in FIG. **9**A. Graft **60** is preferably made of synthetic fibers. By ways of example graft **60** can be made from the material sold under the trademark Dacron by E.I. du Pont de Nemours & Co., Inc. of Wilmington. Del. Body portion **61** and end portion **62** are integrally formed together with springs **64**A–**64**D maintained integrally within the end portion **62** and a portion of the sidewalls of body portion **61** as shown in FIGS. **9**B and **9**E. Graft **60** maintains its shape as shown in FIGS. **9**A–**9**E absent application of external forces thereto and also graft **60** will revert back to such shape upon termination of such external forces thereto.

Graft **60** is positioned within the open central lumen defined in laparoscope **37**. In order to achieve the above, graft **60** is preferably rolled into a substantially cylindrical shape as shown in FIGS. **10**A and **10**B. End portion **62** of graft **60** is manipulated to lie substantially parallel to body portion **61** of graft **60** while graft **60** is in its rolled configuration as shown in FIG. **10**A. The outer diameter of graft **60**, in its rolled configuration, from point W to point Y is larger than the outer diameter of the rolled graft from point Y to point Z as shown in FIG. **10**A. The above is due to the angular construction of end portion **62** as shown in FIG. **9**A. The outer diameter of the rolled graft from point W to point Y is slightly smaller than the inner diameter of laparoscope **37**. As a result, in its rolled configuration, graft **60** can be positioned within the open central lumen of laparoscope **37**. Moreover, graft **60** can be maintained in its rolled configuration while positioned in the central lumen of laparoscope **37** due to the inner diameter thereof. Graft **60** is then inserted into the proximal end of the central lumen of laparoscope **37** and advanced until its full length is entirely therein. A plunger **82** is insertable into the central lumen of laparoscope **37** as shown in FIGS. **11**A and **11**B. Plunger **82** has a length sufficient to span the length of laparoscope **37**. Plunger **82** enables an operator to selectively position graft **60** within body **10**. FIGS. **11**A and **12** show graft **60** positioned in the distal portion of the central lumen of laparoscope **37** after being advanced by plunger **82**. Laparoscope **37** with graft **60** contained therein is then advanced and manipulated such that the distal end of the laparoscope is advanced through the communicating aperture near upstream site **21** and into isolated region **40**. While the

plunger is held stationary, laparoscope **37** is then withdrawn axially over plunger **82** and graft **60** in the direction of arrow **84** as sequentially shown in FIGS. **13**–**15**. This allows graft **60** in its rolled configuration to be delivered out the distal end of laparoscope **37**. FIG. **15** shows end portion **62** of graft **60** positioned within upstream isolated region **40** and end portion **63** of graft **60** positioned at downstream site **31**. Since graft **60** is no longer held in its rolled configuration by the inner diameter of the open central lumen of laparoscope **37**, graft **60** becomes unrolled and reverts to its prerolled configuration as shown in FIG. **16**. Injection of a saline solution into graft **60**, via end portion **63**, may be performed to facilitate the reverting of graft **60** to its prerolled configuration. Alternatively, an additional laparoscope may be used to manipulate graft **60** to its prerolled configuration. Alternatively, a balloon-tip catheter may be advanced into graft **60** via end portion **63** and the graft converted to its prerolled configuration by inflation and deflation of the balloon along various segments of the graft.

Also shown in FIG. **16**, end portion **62** of graft **60** is positioned within upstream isolated region **40** near upstream site **21** and end portion **63** of graft **60** is positioned at downstream site **31** while body portion **61** of graft **60** is positioned outside of blood vessel **11**. Note that end portion **62** has also reverted back to its prerolled configuration so that such end portion is outwardly extending relative to body portion **61** of graft **60**.

Another step according to the preferred method of the present invention includes forming an anastomosis between end portion **62** of graft **60** and blood vessel **11** near upstream site **21**.

A balloon-tip catheter **86** having a balloon **88** thereon and further having an expandable stent **90**, in its unexpanded configuration, positioned over balloon **88** is advanced through the open central lumen of catheter **26** until its distal end is located within upstream isolated region **40** near upstream site **21** (see FIG. **17**). Catheter **86** is further advanced until balloon **88** is positioned substantially adjacent end portion **62** of graft **60** as shown in FIG. **17**. Balloon **88** is then inflated to expand stent **90** to its expanded configuration such that end portion **62** is secured between stent **90** and the sidewall of blood vessel **11** near upstream site **21** as shown in FIG. **18**. Balloon **88** is then deflated and catheter **86** is then removed from body **10** via the central lumen of catheter **26**. FIG. **19**A shows body **10** after catheter **86** is removed therefrom. Moreover, FIGS. **20**A–**20**C show end portion **62** of graft **60** being forced into the sidewall of blood vessel **11** by stent **90** (in its expanded configuration) such that graft **60** is secured to blood vessel **11** near upstream site **21** at its end portion **62**.

One stent which may be used, with a minor degree of modification, in carrying out the preferred method of the present invention is disclosed in U.S. Pat. No. 4,776,337 issued to Palmaz on Oct. 11, 1988, the pertinent part of the disclosure of which is herein incorporated by reference. Such modification would be to provide stent **90** with an outer diameter (in its fully expanded configuration) that is larger than the inner diameter of blood vessel **11** near upstream site **21**.

Note that stent **90** includes a plurality of intersecting bars **71** which span the orifice of graft **60** near end portion **62** as shown in FIG. **20**B. Intersecting bars **71** which span the above orifice do not substantially hinder blood flow through the graft orifice as demonstrated by the technical article entitled "Intravascular Stents to Prevent Occlusion and Restenosis After Transluminal Angioplasty" which was published in the Mar. 19, 1987 edition of the periodical "The New England Journal of Medicine," the pertinent part of the disclosure of which is herein incorporated by reference.

Further modification may be readily made to stent **90** whereby stent **90** would have an opening defined in its sidewall which is of similar dimensions to the orifice of graft **60** near end portion **62**. Such opening would have no intersecting bars traversing thereover. The above modification would allow stent **90** to be positioned within blood vessel **11** near upstream site **21** wherein the above opening would be substantially superimposed over the orifice of graft **60** near end portion **62**. This would allow blood to flow through the connection between blood vessel **11** and graft **60** near upstream site **21** in an unimpeded manner.

As a possible additional procedure in order to further ensure the integrity of the anastomosis between end portion **62** of graft **60** and blood vessel **11** near upstream site **21**, a number of sutures **100** may be tied to the sidewall of blood vessel **11** so as to further secure end portion **62** and stent **90** to the sidewall of blood vessel **11** as schematically shown in FIGS. **19**B and **19**C. This is accomplished by inserting a laparoscope **102** (which is similar to laparoscope **37**) having an open central lumen into human body **10** until its distal end is near upstream site **21**. Thereafter, a grasper **104** is advanced through the central lumen of laparoscope **102**. The grasper **104** has in its grasp a curved needle **106** having an end of suture **100** attached thereto as shown in FIG. **19**D. By manipulating the distal end of grasper **104**, the needle **106** and the end of suture **100** are passed through the sidewall of blood vessel **11** and end portion **62** of graft **60** and into blood vessel **11**. With continued manipulation, the needle **106** and the end of suture **100** are then brought back out of blood vessel **11**. The suture **100** is then tied by standard laparoscopic techniques. One article that refers to standard laparoscopic techniques for tying sutures is entitled "Laparoscopic Choledocholithotomy" which was published in Volume 1, Number 2, 1991 edition of the "Journal of Laparoendoscopic Surgery" (Mary Ann Liebert, Inc. Publishers), pages 79–82, and another article that refers to standard laparoscopic techniques for tying sutures is entitled "Improvement in Endoscopic Hernioplasty: Transcutaneous Aquadissection of the Musculofascial Defect and Preperitoneal Endoscopic Patch Repair", which was published in Volume 1, Number 2, 1991 edition of the "Journal of Laparoendoscopic Surgery" (Mary Ann Liebert, Inc., Publishers), pages 83–90, the pertinent part of both of the above articles of which is herein incorporated by reference. A number of other sutures **100** are then tied to the sidewall of blood vessel **11** and end portion **62** of graft **60** in a manner similar to that hereinbefore described so as to further secure end portion **62** to the sidewall of blood vessel **11** as schematically shown in FIGS. **19**B and **19**C. One or more additional laparoscopes and associated laparoscopic operating instruments may be employed using standard laparoscopic techniques to assist in the above suturing procedure. Of course, sutures **100** may be sewn in a conventional running fashion so as to secure end portion **62** to the sidewall of blood vessel **11**. Also, end portion **62** may be sutured to the sidewall of blood vessel **11** prior to the placement of stent **90** within blood vessel **11**.

Alternatively, the step of forming an anastomosis between end portion **62** of graft **60** and blood vessel **11** near upstream site **21** may be accomplished by suturing alone (i.e. without the use of stent **90**). In particular, once end portion **62** of graft **60** is positioned within upstream isolated region **40** near upstream site **21** as shown in FIG. **16**, end portion **62** is sutured to the sidewall of blood vessel **11** as schematically shown in FIGS. **19**E and **19**F. Note that in this alternative

step, end portion **62** is sutured to an interior portion of blood vessel **11** as schematically shown in FIGS. **19**E and **19**F. Also note that end portion **62** is sutured to the sidewall of blood vessel **11** so as to be positioned substantially adjacent a portion of the sidewall of blood vessel **11** which substantially surrounds the arteriotomy. This is accomplished by tying a number of sutures **110** to the sidewall of blood vessel **11** and end portion **62** of graft **60** so as to secure end portion **62** to the sidewall of blood vessel **11** as schematically shown in FIGS. **19**E and **19**F. The sutures **110** shown in FIGS. **19**E and **19**F are applied in the same manner as the sutures **100** shown in FIGS. **19**B, **19**C and **19**D were applied as described above. Of course, sutures **110** may be sewn in a conventional running fashion so as to secure end portion **62** to the sidewall of blood vessel **11**.

As a further alternative, the end portion **62** of graft **60** need not be positioned in upstream isolated region **40** but rather end portion **62** may be positioned adjacent the sidewall of blood vessel **11** so that the communicating aperture (i.e. the arteriotomy) in the sidewall of blood vessel **11** near upstream site **21** is aligned with the central passage of graft **60**. At this position, end portion **62** is sutured to the sidewall of blood vessel as schematically shown in FIGS. **19**G and **19**H. Note that in this further alternative step, end portion **62** is sutured to an exterior portion of blood vessel **11** as schematically shown in FIGS. **19**G and **19**H. Also note that end portion **62** is sutured to the sidewall of blood vessel **11** so as to be positioned substantially adjacent a portion of the sidewall of blood vessel **11** which substantially surrounds the arteriotomy. This is accomplished by tying a number of sutures **120** to the sidewall of blood vessel **11** and end portion **62** of graft **60** so as to secure end portion **62** to the sidewall of blood vessel **11** as schematically shown in FIGS. **19**G and **19**H. The sutures **120** shown in FIGS. **19**G and **19**H are applied in the same manner as the sutures **100** shown in FIGS. **19**B, **19**C and **19**D were applied as described above. Of course, sutures **120** may be sewn in a conventional running fashion so as to secure end portion **62** to the sidewall of blood vessel **11**.

The remainder of the preferred method of the present invention is performed using standard surgical techniques. A book which discloses various standard surgical techniques is entitled "Color Atlas of Vascular Surgery." authored by John S. P. Lumley, published by Wolfe Medical Publications Ltd. of Baltimore, Md. (1986), printed by W. S. Cowell, Ltd. of Ipswich, United Kingdom, and the pertinent part of the disclosure of which is herein incorporated by reference. More specifically, another step according to the preferred method of the present invention comprises isolating a region **50** of the area within blood vessel **11**, located near site **31** downstream of occluded segment **14**, from fluid communication with the rest of the area within the blood vessel. Referring now to FIG. **21**, a pair of surgical clamps **53** and **55** are positioned on blood vessel **11**, one being placed upstream of isolated region **50** and the other being placed downstream of isolated region **50**.

Another step according to the method of the present invention comprises making an arteriotomy in the sidewall of blood vessel **11**, near downstream site **31**, to create a communicating aperture between downstream isolated region **50** and the outside of the blood vessel **11**. End portion **63** of graft **60** is retracted by surgical forceps (not shown) to expose blood vessel **11** near downstream site **31** (see FIG. **22**). A scalpel puncture is then made in blood vessel **11** near downstream site **31** and thereafter the puncture is extended to the appropriate length with a pair of surgical scissors. FIG. **22** shows the communicating aperture defined in the sidewall of blood vessel **11**, near downstream site **31**.

Another step according to the preferred method of the present invention comprises forming an anastomosis between end portion **63** of graft **60** and blood vessel **11** near downstream site **31**. Graft **60** is then cut to an appropriate length and thereafter end portion **63** is cut an appropriate shape for attachment to blood vessel **11**. End portion **63** of graft **60** is then surgically stitched with suture **65** to blood vessel **11** near downstream site **31** as shown in FIG. **23**.

Clamps **53** and **55** are then removed from blood vessel **11**, and moreover, balloons **24** and **28** are then deflated and thereafter catheters **22** and **26** are removed from body **10** as shown in FIG. **24**. This allows blood to flow to former upstream isolated region **40**. Once blood flow reaches former upstream isolated region **40**, a flow of blood will enter graft **60** and flow therethrough to former downstream isolated region **50** thereby bypassing occluded segment **14**. Consequently, proper blood flow will now exist in body **10** from point C within aorta **16** to point D within right common femoral artery **18** as a result of performing the above described method of bypass of occluded segment **14**.

While the invention has been described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments and methods have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

For instance, it is possible that left common femoral artery **30** and left inguinal ligament **29** could be exposed via a surgical incision similar to that of incision **17** as hereinbefore described. Thereafter, a Y-shaped graft could be utilized instead of graft **60** as hereinbefore disclosed. The Y-shaped graft could be advanced in a rolled configuration through laparoscope **37** and delivered to a position substantially adjacent blood vessel **11** similar in manner to that hereinbefore described. An additional laparoscope could be inserted into human body **10** through the opening defined between left common femoral artery **30** and left inguinal ligament **29** in a manner substantially similar to that hereinbefore described with respect to the insertion of laparoscope **37** into human body **10**. The additional laparoscope could be advanced toward the left limb of the Y-shaped graft and thereafter used to grasp such limb and pull it toward left common femoral artery **30** and subsequently out of the surgical incision near the left common femoral artery. The end portion of the left limb of the Y-shaped graft could be cut to an appropriate length and shape, and thereafter, an anastomosis could be made between such end portion and left common femoral artery **30** similar in manner to that hereinbefore described with regard to right common femoral artery **18** and end portion **63** of graft **60**.

Moreover, for example, in an alternative embodiment of the present invention, it is possible that a graft **200** may be utilized which would be similar to graft **60** hereinbefore described, however, both end portions of such graft **200** could be similar in structure to end portion **62** of graft **60** (see FIGS. **29**–**33**). In other words, each graft end could posses an end portion that is resiliently maintained outwardly extending relative to the body portion of the graft **200**. A catheter **202** could be placed into blood vessel **11** at right femoral artery **18** and advanced toward occluded segment **14** (see FIG. **25**). Prior to arriving at occluded segment **14**, the distal end of the catheter **202** could be manipulated and guided out of blood vessel **11** through a puncture site **204** laparoscopically created in the blood

vessel in a manner similar to that hereinbefore described (see FIG. **26**). The catheter **202** could then be advanced substantially adjacent blood vessel **11** over and past occluded segment **14** (see FIG. **27**). One or more additional laparoscopes could assist in the above advancement (see also FIG. **27**). The distal end of the catheter **202** could then be manipulated and guided to reenter blood vessel **11** at a site upstream of occluded segment **14** through a puncture site **206** laparoscopically created in blood vessel **11** in a manner similar to that hereinbefore described (see FIG. **28**). The graft **200** having a resiliently outwardly extending end portion at each end thereof could then be advanced in a rolled configuration through the catheter **202** and delivered to a position substantially adjacent blood vessel **11** similar in manner to that hereinbefore described with respect to graft **60** and laparoscope **37** (see FIGS. **29**, **30**, **31**). The graft **200** could have a predetermined length equal to a length slightly larger than the distance between the puncture site **206** located upstream of occluded segment **14** and the puncture site **204** located downstream of occluded segment **14**. As a result, the distal end portion of the graft **200** could be positioned within blood vessel **11** at a location upstream of occluded segment **14** and the proximal end portion of the graft **200** could be positioned within blood vessel **11** at a location downstream of occluded segment **14** while the body portion of the graft **200** could be positioned substantially adjacent and outside of blood vessel **11** (see FIGS. **29**, **30**, **31**). Of course, an area within the blood vessel near each end portion of the graft **200** could be isolated from fluid communication with the rest of the area within the blood vessel in a manner substantially similar to that hereinbefore described with respect to upstream isolated region **40**. After being advanced out of the distal end of the catheter **202**, the graft **200** (including each outwardly extending end portion) could revert back to its prerolled configuration as hereinbefore described with respect to graft **60** (see FIG. **32**). Thereafter, a stent **208** could be placed, in an expanded configuration, adjacent each of the end portions of the graft **200** within blood vessel **11** in order to secure such end portions of the graft **200** to blood vessel **11** as hereinbefore described with respect to stent **90** and end portion **62** of graft **60** (see FIG. **33**).

The invention claimed is:

1. A method of bypassing a restriction in an artery of a mammal, the method comprising:

providing a graft having a body portion with a first end, a second end and a lumen therebetween;

forming a first aperture in a first artery;

forming a second aperture in a second artery distal of the restriction;

placing the graft between the first aperture in the first artery and the second aperture in the second artery;

inserting an expandable stent intravascularly from a location remote from the first aperture for positioning in the first artery at the location of the first aperture;

expanding the stent to connect the first end of the graft within the first artery; and

attaching the second end of the graft to the second aperture in the second artery.

2. The method of claim **1** wherein the first artery is the aorta.

3. The method of claim **1** wherein the second end of the graft is attached by suturing.

4. The method of claim **1** wherein expanding the stent comprises:

expanding the stent radially outward to lie against an interior wall of the first artery.

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